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REPORT NO. 94-1399-70

REPEATED INSULT PATCH TEST WITH IN FINISHED OIL (C 1234-24-2)

FOR

COMPANY SANITIZED

BEH9-96-13683 88960000 1635



HILL TOP RESEARCH, INC.
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REPEATED INSULT PATCH TEST WITH

<u>SUMMARY</u>

A Repeated Insult Patch Test was conducted in Miamiville and Morwood, Ohio by Hill Top Research, Inc., for

It investigated the skin sensitization actually in finished oil (C 1234-24-2), a 50% dilution in mineral oil. Test Article A, (Mineral Oil U.S.P.) was also tested. All exposures were by 24 ± 1 hour contact under semi occluded patches. Patches were applied to sites on the upper arm. Any incidence of skin irritation observed to the test articles was also reported. The prefix code for these test articles was 94-1399-70.

| HTR CODE | SPONSOR CODE |
|----------|-------------------------|
| Α, | Mineral Oil U.S.P. |
| В | |
| С | .) in finished oil, 50% |

Thirty subjects were enrolled in a pilot study to determine the appropriate dose to be used in the definitive study. Of these thirty subjects, fifteen received mineral oil and in finished oil (C 1234-24-2) and fifteen received mineral oil and inished on (C 1234-24-2) (50%). Two subjects withdrew from the study for reasons unrelated to the test articles. Twenty-eight subjects completed the pilot study.

During the pilot study, one subject exhibited mild erythema at the eighth induction application to the mineral oil. This response was resolved by the ninth application. No other responses were observed during induction to the test articles. During challenge no reactions were observed for the test articles. Based on this observation, doi! (C 1234-24-2) was applied neat in the definitive study (designated as 1

SUMMARY (Continued)

One hundred-six subjects entered the definitive study. Seventeen subjects withdrew for reasons unrelated to the study. Eighty-nine subjects completed the definitive study.

In addition to in finished oil (C 1234-20-70), mineral oil was tested as a control for the definitive study. During the definitive study, one subject exhibited mild erythema to in finished oil (C 1234-24-2) at the second induction visit. This response was resolved by une fourth induction visit. A second subject exhibited mild erythema at the eighth induction visit. This response was resolved by the ninth induction visit. No other responses were observed during induction.

After the two-week rest period, 89 subjects reported to the test site on October 17, 1994, to receive their challenge application. Before application it was observed that Subject No. 31 exhibited mild erythema with a papular response covering the entire front area of the right arm (original patch site included). The subject stated that she had been working in her garden pulling weeds on Saturday, October 15, 1994 and that the response began on Sunday, October 16, 1994. Based on this observation, only the naive site (left arm) was patched for challenge. The subject exhibited no reaction at the 48-hour evaluation. At the 96-hour evaluation she exhibited mild erythema with papules, edema, and spreading to in finished oil (C 1234-24-2). The site patched with mineral oil (the control) was clea.

Under the conditions of the study, the reactions exhibited by Subject No. 31 are indicative of clinical sensitization.

TITLE

Repeated Insult Patch Test with

in finished oil (C 1234-24-2)

(Modified Draize Procedure)

OBJECTIVE

To evaluate ... in finished oil (C 1234-24-2) for the induction of contact sensitization by repetitive application to the skin of human subjects and to report any irritation observed with the test articles.

SPONSOR AND MONITOR

INVESTIGATIVE ORGANIZATION, TEST LOCATION AND PERSONNEL

Organization:

Hill Top Research, Inc.

Location:

Miamiville, Ohio 45147

Investigator:

Robert A. Harper, Ph.D.

Test Operation Supervisor:

Martha E. Plaza, M.B.A.

Senior Project Leader:

Bonnie Rue

CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, was reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board was obtained on July 12, 1994, prior to the initiation of the investigation (see Appendix IV).

GOOD CLINICAL PRACTICE STATEMENT

This study was conducted in accordance with Good Clinical Practices as outlined in Title 21 of the Code of Federal Regulation parts 50 and 56.

PROTOCOL

The study protocol, furnished by the Investigator and approved by the Study Sponsor, was followed (see Appendix V).

1.

AMENDMENT TO PROTOCOL

There were three amendments to the protocol (shown in Appendix V).

DEVIATIONS FROM PROTOCOL

See Appendix II.

In the opinion of the Investigator, these deviations did not affect the outcome or integrity of the study.

TEST SUBJECTS

Prior to entrance into the study, written informed consent was obtained from each subject using the form shown in the protocol (see Appendix V).

Urine pregnancy tests were given to all females of child bearing potential at study start, week four and the beginning of Challenge (Week 6).

One hundred thirty six subjects who met the inclusion criteria started the study. One hundred sixteen subjects completed the study in both the pilot and definitive study.

Those subjects who did not complete the study and the reasons why are shown in Appendix III.

STUDY SCHEDULE

PILOT STUDY

Subject Nos.:

1 through 30

Study Initiated:

July 18, 1994

Study Completed:

August 26, 1994

STUDY SCHEDULE (Continued)

DEFINITIVE STUDY

| Subject Nos. | Study Initiated | Study Completed |
|-----------------|--------------------|-------------------|
| 31 through 114 | September 12, 1994 | October 21, 1994 |
| 115 through 129 | September 14, 1994 | October 21, 1994 |
| 130 through 136 | September 16, 1994 | October 21, 1994 |
| Rechailenge | | |
| Subject No. 31 | December 12, 1994 | December 16, 1994 |

TEST ARTICLES/APPLICATION

The Test Sponsor furnished 885.2gm of a finished oil (C 1234-24-2) for the study on July 1, 1994.

The Investigator organization made a 50% dilution of a finished oil (C 1234-24-2) with mineral oil (Test Article C).

Test Articles B and C were dispensed at 0.1ml using an Eppendorf® semi-automatic pipette to the Webril® portion of the Professional Medical Products semi-occluded patch.

The Investigator organization provided Test Article A, Mineral Oil U.S.P., which was dispensed at 0.1 ml using an Eppendorf® semi-automatic pipette.

Test Article C was evaluated during the pilot study only. Test Article A (mineral oil) and Test Article B nished oil (C 1234-24-2) were evaluated on both the pilot and definitive studies.

ADVERSE EVENTS REPORT

There were no adverse events in this study.

RESULTS

Transcribed data for each individual subject are presented in Tables 1A through 1C. Summary totals for the complete panel of subjects observed during Induction and Challenge are located in these tables (see Appendix I).

During induction in the pilot study, Subject No. 22 exhibited mild erythema to mineral oil at the eighth induction evaluation and the response was clear by the ninth induction visit. No other responses were observed during the pilot study.

During the definitive study only the neat in finished oil (C 1234-24-2) was tested along with mineral oil. Subject No. 78 exhibited mild erythema to in finished oil (C 1234-24-2) at the eighth induction evaluation and the response was clear by the ninth induction visit. Subject No. 79 exhibited mild erythema to in finished oil (C 1234-24-2) at the second induction evaluation and the response was resource by the fourth induction visit. These were the only responses seen during the induction phase.

After the two-week rest period, 89 subjects reported to the test site on October 17, 1994, to receive their challenge application. It was observed for Subject No. 31 that mild erythema with a papular response was covering the entire front area of the right arm, including the original patch site. Upon questioning, the subject stated that she had been working in the garden pulling weeds on Saturday, October 15, 1994. The foilowing day, (Sunday, October 16, 1994) the response was noted by the subject. Based on this observation only the adjacent site (left arm) was patched for challenge. No responses were observed to in finished oil (C 1234-24-2) at the 48-hour evaluation. By the 96-hour evaluation, mud erythema with papules and edema with spreading were observed. No responses were observed at the site patched with mineral oil throughout the challenge for this subject.

On December 12 1994 after a seven week rest period, Subject No. 31 received a Confirmatory Rechallenge. in finished oil (C 1234-24-2) was patched on the original site (right arm) and a naive site (lower right back). The subject exhibited no response at the 48-hour evaluation. At the 96-hour evaluation the subject exhibited mild erythema with papules on both the original and the naive sites. The subject called on December 19, 1994 stating the reaction on her back was spreading with itching. The subject was evaluated that afternoon. On the original site (right arm), the response pattern remained the same as seen at the 96-hour evaluation. On the naive site (lower back) the response pattern exhibited mild erythema with definite spreading and itching.

RESULTS (Continued)

The reactions were clear by January 6, 1995.

CONCLUSIONS

Under the conditions of the study, the reactions exhibited by Subject No. 31 in finished oil (C 1234-24-2) are indicative of clinical sensitization.

Submitted for: HILL TOP RESEARCH, INC.

Investigator

| By: | Berne Lui | 2-28 95 |
|--------------|----------------------------|---------|
| | Bonnie Rue | Date |
| | Senior Project Leader | |
| • | Marche E. Plaza | 2/28/95 |
| | Martha E. Plaza, M.B.A | Date |
| | Test Operations Supervisor | 1 1 |
| Approved by: | Kolund A. Harper | 3/1/95 |
| | Robert A. Harper, Ph.D. | Date |

Jim Kreuzmann Date
General Manager

Quality Assurance Statement

This study was inspected in accordance with the Standard Operating Procedures of the Hill Top Companies. To assure compliance with the study protocol, the Quality Assurance Unit performed an inspection during the conduct of the study and completed an audit of the study records and the final report.

QA findings derived form the inspections during the conduct of the study and from the inspection of the final report are documented and have been reported to the appropriate personnel.

| Date of Inspection | Auditor | Critical Phase Inspected |
|--------------------|-------------------|--------------------------|
| 7-20-94 | Elizabeth Camacho | Scoring |

| Report | Date Reviewed |
|--------|---------------|
| Draft | 11-16-94 |
| Final | 3-2-95 |

Reviewe by:

Auditor, Quality Assurance

Date

APPENDIX I

(Total number of pages = 16)

Data Tables

(Pilot and Definitive)

Table 1A. Individual reaction scores following the application of test material. Sample: A (MINERAL OIL)

| | Sample | Bample: A (MINERAL OIL) | ral oil) | | | | Applica | Application Number | raqui | | | | | | | | | | | | |
|---------------------------------------|---|---|---|--|---|--|-------------------------------------|--------------------|-----------------|---------------|--|--|--|---|--|---|--|---------------------------------------|----------------|-------|----------|
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| 5=4 | 9 | . | | | - | | 0 | | | 0 | | 0 | | 0 | | | | 0 | 0 | 0 | • |
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| m | 0 | 0 | 0 | 3 | > (| | • | | | | | | | • | | | | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | | > (| | | | | • • | | | | | | | 0 | c | |
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| 9 6 | | | c | 0 | 0 | | 0 | | | 0 | | 0 | | . | | | | . | > 0 | | > < |
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| 3 | > 6 | > 6 | . c | | 0 | | 0 | | | 0 | | 0 | | 0 | | | | 0 | 0 | 9 | . |
| (3) | SZ . | 5 | D (| ۰ د | | | 0 | | | 0 | | 0 | | 0 | | | | 0 | 0 | 0 | 0 |
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| कर्ण इन्दे | 0 | 0 | 0 | 0 | o (| | . | | | | | | | 0 | | | | 0 | 0 | 0 | |
| 12 | ٥ | 0 | 0 | 0 | 0 | | > 6 | | | | | | | | | | | 0 | 0 | 0 | |
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| 4 | 0 | 0 | 0 | 0 | 0 | | 0 | | | > • | | > 4 | | | | | | · c | • | c | 0 |
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| 1 6 | • | | · c | 0 | 0 | | 0 | | | 0 | | 0 | | 0 | | | | • | > 0 | | > < |
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| es es | 0 | 0 | 0 | 0 | 0 | | 0 | • | | > | | 4 | | • | | | | | | | |
| 60 | 0 | ٥ | 0 | 0 | 9 | | Dr | Dropped | | , | | • | | • | | | | 0 | 0 | 0 | 0 |
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| | C | | 0 | 0 | 0 | | 0 | | | 0 | | 0 | | o : | | • | | | , c | | |
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| * * * * * * * * * * * * * * * * * * * | | site; M oring of o | original site; M * first moved site; M1 * second first scoring of original and adjacent challenge sites | site; Mi acent chall | second snge sites | moved site (48 hours) | <u> </u> | | ٥, ١٨, | 8 | nd scor! | ing of c | second scoring of challenge sites (96 hours) | ites (| 36 hours | _ | | | | | |
| | m Mo visible rest Mild resction m Moderate resct m Strong to seve m Edema - swell: m Paphles - red m Vesicles - sm Smm or less m Bulla resction m Weeping - res fluid cozing fluid cozing | Mid reaction and/or e Mid reaction - macular eryt Moderate reaction - macular Strong to severe reaction - Edema - swelling, spongy fee Papules - red, solid, pinpoi Vesicles - small elevation Smm or less Bulla reaction - fluid-fills Spreading - evidence of the Weeping - result of a vesic Iluid cosing or covering pat Induration - solil, elevated | m No visible reaction and/or erythems (faint, but definite pink) # Hild reaction - mecular erythems (definite redness, similat to a sunburn) # Moderate reaction - macular erythems (definite redness, similat to a sunburn) # Moderate reaction - macular erythems (very intense redness) # Moderate reaction - macular erythems (very intense redness) # Papules - red, solid, pinpoint elevations, granular feeling # Papules - red, solid, pinpoint elevations, granular feeling # Westcles - small elevation containing serous fluid (blister-like), diameter # Manula reaction - fluid-filled lesion greater than 0.5cm in diameter # Mesping - result of a vesicular or bulla reaction - serous exudate - clear # Mesping - result of a vesicular or bulla reaction - serous exudate - clear # Induration - solii, elevated, hardened, thickening | income (faint, but definite pink) erythema (definite redness, similat to macular erythema (very intense redness) ling when palpated int elevations, granular feeling containing serous fluid (blister-like), ad leston greater than 0.5cm in diameter resction beyond the test site lar or bulla reaction - serous exudate th site it hardened, thickening | definite te redness, (very inte ed renular fer fluid (bl; the test si ction - sei | pink) smallat smae redni sling later-lik s in diam | to a su sss) b), diam ster | nburn) eter | א אאנייו הדטמעע | | dlazing Real, dried film of Ryperpigmentation (r Rypopigmentation (lo Fissuring - grooves Residual reaction to Test patch lost soon Patch omitted due to Applied to adjacent irrelevent to test a | film of tation (i grooved grooved action i lost social addeen addeen to test | dlazing Realing Real, died film of werous exudate of vesicular or bulla reaction Ryperphymentation (reddish-brown discoloration of test site) Ryperphymentation (loss of visible phymentation at test site) Riseuring — grooves in the superficial layers of the skin Absence Residual reaction to earlier application after absence (Not included in totals) Test patch lost soon after application (Not included in score totals) Retch omitted due to previous strong test reaction(s) Applied to adjecent site because of adhesive reaction or for other reasons irrelevant to test material reactions Patch omitted for reasons unrelated to the test | udate (own dilble p perfic application use of central calated calated calated calated | of vesic scolorat lgmentat lal laye ation af ion (Not g test r g test r g test r | ular ox ion of ion at rs of t rs of t holiu esction esction | or bulla rea t test site) the skin the skin asence (Not ided in scox on(s) | esction e) t includ ore tota or other | dd in reasc | total | î |

- No minth grade

Table 1A. Group total reaction scores following the application of test material. Sample: A (MINERAL OIL)

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1990 - No minth grade

Table 18. Individual reaction scores following the application of test material. Sample: B $(SP-7053\ in\ Finished\ Oil)$

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|--------------|---------------------|--|---------------|-----------|------------------------|--|---------|----------------|------------|-----------|--------------------|-------|----------|-------------|-----------|---------|----------|--------|---|----------|--------|---------|--------|--------|---------------|---------------|-----------|---------------|--|
| | | | | | | | | | | A | Application Number | ton M | umber | | | | | | | | | | | | | | : | | |
| 4000 | - | R | | m | | 4 | | ļ | 8 | | | 9 | 1 | | - [| 1 | | 1 | | | ı | 1 | ₽, | | • | Cha | Challenge | | |
| Marker | er O | 0 | ٥ | E | E | 0 | E E | 0 | E | M1 | 0 | I | M | 0 | Y: | T. | 0 | Í T | 0 | X, | E | ט | E | M | 0 | < | ò | Š | |
| • | • | • | c | | | _ | | 0 | | | 0 | | | 0 | | | 0 | | • | | | | | | 0 | 0 | 0 | 0 | |
| ≓ · | . | • | • | | | | | • | | | 0 | | | 0 | | | 0 | | 0 | | | | | | 0 | 0 | 0 | 0 | |
| N | 9 | 9 (| 9 (| | - • | | | • • | | | · c | | | 0 | | | 0 | | • | | | | | | 0 | 0 | 0 | 0 | |
| m | • | 9 | • | | ٠ - | . | | • | | | | | | | | | | | 0 | | | | | | 0 | 0 | 0 | 0 | |
| • | 0 | 0 | 0 | | _ | | | - | | | > 0 | | | • | | | | | | | | | | | · c | C | c | C | |
| មា | 0 | 0 | 0 | | - | _ | | • | | | • | | | . | | | > 0 | | • | | | | | | • • | • • | • • | • • | |
| € | 6 | 0 | 0 | | _ | 6 | | 0 | | | 0 | | | 0 | | | . | | > | | | | | | > < | > 0 | • | • | |
| P | | | ~ e | | - | 6 | | 0 | | | 0 | | | 0 | | | 0 | | 0 | | | | | | - | 9 |) | > (| |
| - 6 | • | | | | _ | _ | | 0 | | | 0 | | | 0 | | | 0 | | 0 | | | | | | 0 | 0 | • | o | |
| 9 (| | > | | | . • | | | 0 | | | 0 | | | 0 | | | 0 | | • | | | | | | 0 | 0 | • | 0 | |
| 37 | | > (| • | | | | | • • | | | | | | 0 | | | 0 | | 0 | | | | | | 0 | 0 | 0 | 0 | |
| 9 | 0 | 9 (| > (| | - 6 | , | | • • | | | | | | 0 | | | 0 | | 0 | | | | | | 0 | 0 | 0 | 0 | |
| 6-4 6-4 | • | 9 | • | | | > - | | • | | | • < | | | | | | · c | | 0 | | | | | | 0 | 0 | 0 | ٥ | |
| 23 | 0 | 0 | 0 | | | 0 | | > | | | > ' | | | > (| | | • | | • • | | | | | | C | C | c | 0 | |
| - Car | 0 | 0 | 0 | | _ | 0 | | 0 | | | 0 | | | 0 | | | > | | • | | | | | | • | • | • | • • | |
| 9 6 | é | c | 0 | | _ | 6 | | 0 | | | 0 | | | 0 | | | 0 | | 0 | | | | | | > (| > (| > (| > < | |
| 7 65 4 67 | , > c |) C | | | | | | 0 | | | 0 | | | 0 | | | 0 | | 0 | | | | | | 0 | 9 | 9 | > | |
| 1 | | • | • | | - | | | | | | | | | | | | | | | | | | | | | | | | |
| € | a certainal atta: M | 200 E | | et mo | a first moved site; Mi | E | | = second moved | BOVEG | mite | | | | | | | | | | | | | | | | | | | |
| 4. 0 | a Alret | first scoring of original and adjacent challengs sites | original | and | adjacent | chair. | llenge | sites | (48 hours) | ur@) | | | 0, 'A | 9 | cond | acorin | 30 B | challa | O', A' . second scoring of challenge sites (96 hours) | <u> </u> | mog 9 | (8) | | | | | | | |
| | |) | , | | | | | | | | | | | | | | | | | | | | | | | | | | |
| G | Para Car | me visible reaction and/or erythems | lon and/c | Wile St | thema | | | | | | | | 0 | a 01 | ∞ Glazing | - | | | | | | | | | | | | | |
| 9 87 | | Mild reaction - macular grathems (faint, but definite pink) | Meniar e | rvthe | es (falk | it. | ut def | inite p | ink) | | | | > | 6 6 8 | Peeling | _ | | | | | | | | | | | | | |
| • 6 | | mandarate reaction - maching ervinema (definite reduess, similat to a sunburn) | [112 | . 14 | vthema | (def1: | nite r | edness. | aimil | at to | a sunb | urn) | ບ | 1 BC | ab, d | iried f | 11m o | f sero | Scab, dried film of serous exudate of vesicular or bulla reaction | ate o | f vers | cular | or po | lla re | action | | | | |
| ৪ বশ | | Strong to severe reaction - macular erythema (very intense reduess) | reaction | | cular ei | cythen | (AA) | ry inte | nse re | dnessa | | | 7 | 2 2 3 | rperpi | Igmenta | tion | (redd1 | Byperpigmentation (reddish-brown discoloration of test site) | n dis | color | ation o | or tem | t mite | = 1 | | | | |
| • | | | | | | | • | 1 | | | | | Æ | Š. | popig | pmentat | Jon (| 1088 0 | Hypopigmentation (loss of visible pigmentation at test site) | le pi | greent | tion a | it tem | t ølte | • | | | | |
| 8 | | Edams - swelling, spongy (selling when palpated | ADUCUE | £003.41 | ng when | 2810 | at ed | | | | | | 64 | | seuri | lng - g | TOOV® | e in t | Fissuring - grooves in the superficial layers of the skin | ríici | al lay | rere of | the | | | | | | |
| 9 6 | | massa - creating as a second of a second o | | 42424 | 400010 | 2000 | nran: | Par Pas | lina | | | | | | | | | | | | | | | | | | | | |
| 14 3 | | regulars told board from containing services for the follows. Jan 1980. diameter | | | | | | 4d (b)4 | ater-1 | (ke) | diamet | L. | ŧ | 2 | Absence | | | | | | | | | | | • | | • | |
| > | | 44000 | | | | | | | | | | ! | æ | 6 | e 1 due | al reac | tion | to ear | Residual reaction to earlier application after absence (Not included in totals) | plica | tion (| ifter (| paenc | e (Not | . Anclu | d@d 21 | n tot | ale) | |
| ŧ | | | 40 66.00 | 91 | Tondon. | 40000 | 9 | 6 | 4 2 4 | m m m d m | | | | 8 | at Da | atch lo | at so | on aft | year natch lost soon after application (Not included in score totals) | 1cat1 | on (M | ot incl | Luded | in sec | re tot | als) | | | |
| | | Welle Restrict Batterstated Assacs Trests to the Assacs and Color and Comments and Color and Col | 73-07-07-9 | TARMIT | A CONTRACTOR A | | | | | | | | * | ā | | and the | 6116 | to pre | Datch contitod due to previous strong test reaction(s) | trond | test | react | lon(a) | | | | | | |
| | | Syrabing - syldends of the restrion bayon the lest site | TO BOUR | 5538 A.S. | SCEACH. | Der Cur | | | | 400 | 9 | 8 | . | B | 100 | 4 to ad | 1acen | t alto | annian to adjacent afte because of adhesive reaction or for other reasons | 0.0 | adhee | IVO FOL | action | or fo | x othe | r res | sons | | |
| | Buideen a | Weeping - result of a Vesicular of Dulla resction - serous exulate - Clear stall scales at somether stall with | TOV BY NOT | ACUAM | H 05 Pu | 7 T 18 18 18 18 18 18 18 18 18 18 18 18 18 | 773088 | | | | | 4 | • | ı | 7007 | vent to | test | mater | hypared to majacing first selections | ction | | | | | | | | | |
| | | risis coulng or covering parch sits | COVERING | parcu | | | • | | | | | | 3 | | | 4444 | | 4000 | tildiction to cold minimum three at the test | ated | to the | tent | | | | | | | |
| \$=6 | s Indurat | Indaration - solid, elevated, hardenad, thickening | id, eleve | sted, | hardens | d, ch | 1cken 1 | DG. | | | | | Į | S | בכם ם | | 101 | | | 3 | } | | | | | | | | |

Table 18. Group total reaction scores following the application of test material. Sample: 8 (8P-7053 in Finished Oil)

| | Scores | | | ~ | ત્વ | m | Bub Total | | Orop | • | e s | × | A | Ø, | gos Total | Grand | | | <u></u> | A | | | * | × | Letter Totale | 8 . | 9 | 0,3 = 21x | 8 | | | 8 8 8 | |
|-----------|---------------|----------|-----|---------------|---------------|----------|--------------|--------|-------------|-------------|------------|---------------|---------------|----|--------------|----------|----|---------------|------------|----------|-----|-----|----------|-------------|------------------|------------|---|--|---|--|--|--|--|
| | 10 | | | > | 0 | 0 | * | | 9 | 0 | 0 | 0 | – 1 | 9 | # 4 | , s | ; | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | 9 | - original alte, M | first scoring of original and adjacent challenge sites (48 hou | Me visible resction and/or erythems | Wild resetton - mecular erythema (faint, but definite pink) | Moderate restrich - macular erythema (ostinica rechema) shella Mircha to mayers restrich - macular erythema (very intense red | Edema - swelling, spongy feeling when palpated Papules - red, solid, pinpoint elevations, granular feeling Vesicles - small elevation containing serous [id (blister-li | Bulls resetton - fluid-filled lesion greater than 0.5cm in dia |
| ~ | 0 | E | 7 | . | 0 | 0 | 8 | , | 0 | 9 | 0 | 0 | 9 | 0 | 0 | 5 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | ٥ | 9 | 91693 |)z ing | e rea | rt.100 | | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | ret 10n |
| | [Z | c | | > (| 9 | 0 | 0 | (| 9 | 0 | 0 | 0 | 0 | 0 | • | | | 0 | 0 | 0 | 0 | ٥ | 0 | 0 | 0 | ٥ | X | of ori | orton | . 1960 | zor zor | | - (1) |
| | 0 | 6 | 3 6 | > 6 | 9 | 0 | 15 | , | - 0 (| - | 0 | 0 | 0 | 9 | 0 | · | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | E ELE | (6 188) | and/c | ler e | macu. | Pongy 1. Pli | 11d-£1 |
| e | l | c | | > < | > | 0 | 0 | • |) | 9 | 0 | 0 | 0 (| 9 | 0 | 15 | , | 9 1 | 9 | 0 | 0 | 0 | 0 | 0 | • | 0 |) (NO | 926 | 120 14 | ryth | | feeld point m con | 11100 |
| ! | E | 0 | | • | > | 0 | 0 | • | > | 9 | 0 | 0 | o (| 5 | | | | 0 | 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 78 P&A | edjec. | thems | | ythem quiez | ing wh : elevi | 10010 |
| | ٥ | 85 | } = |) (| > | 0 | en | c | > | 5 (| 0 | • | 9 6 | > | 0 | | | 0 (| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - first moved site; Hi | ant ch | | 12nt, | | en pal ations | n gree |
| 4 | Z. | 0 | · c | • • | > (| 0 | 0 | • | > 0 | , | ۰ د | 0 | 0 0 | > | 0 | 15 | | . | - | 0 | 0 | 0 | 0 | 0 | 0 | • | | allen | , | But d | | pated gran | tent t |
| 1 | M | | | | • | 0 | | c | > < | > | ۰ د | o (| . | • | 0 | | | 5 6 | . | 9 | 0 | 0 | 0 | 0 | 0 | ٥ | a second moved site | 30 01t | , | afinit | redne | hulez Lid (| han O. |
| | 0 | 85 | 0 | | | | 15 | • | > < | > 6 | 5 6 | > (| > < | > | • | ~ | • | > 6 | 5 (| ۰ ، | 0 | 0 | 0 | 0 | 0 | 0 | nd Boy | 98 (4) | , | e pini | atenet | feell blist | Scm 11 |
| 8 | E W | • | 0 | | | | | - - | | | | | • • | | 0 | s | | • · | | | | | | • | 0 | • | 'ed e1 | nou nou | | () | reller Fødn | 16 11.11k | diam |
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| on Muse | M M | 0 | 0 | 0 | | | 0 | 0 | | | | | | | 0 | μΩ | • | | | | | | 9 (| 9 | | 0 | • | - | | 5 | f 11 71 | ≜ 4 | |
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| | <u>.</u> 0 | 15 0 | 0 | 0 | | | 15 0 | 0 | | _ | - | | | | | 1 | • | | | | | | | - - | 0 | 0 | | | A Wee | 110 | | | - 44 |
| 1 | I I | 0 | 0 | 0 | | | 0 | 0 | _ | | | | | | 0 | ķΩ | - | , , | • | | | | . | > | 0 | 0 | Sympton 196 meter and an extension 196 hours | | Weeping - result of a vesicular or bulls reaction | finid bozing of covering paten site Induration - solid, slevated, harde | 8 4 2 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 | Absence Residual reaction to earlier application after absenc Test patch lost soon after application (Not included Patch omitted due to previous strong test reaction(s) Applied to adjacent aits because of adhesive reaction | irrelevant to test material reactions |
| | 0 | 15 | • | • | _ | | 15 | | _ | | | | | | | | _ | . ~ | | | | | | | | | 1 | SOL ANY | resu | 23 mg 0 | l | react oh los kted | 14 40 |
| 1 | X. | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | | | 0 | | 0 | 15 | .0 | | | | | | | | 0 | 0 | , , | 5 | lt of | r cove | | ton to t soon dus to | test s |
| 1 | M | 0 | 0 | 0 | | | • | 0 | 0 | | | | | | 0 | | 0 | | | | | | | | 0 | • | ָבֶּבְּרָבְּיִבְּיִבְּיִבְּיִבְּיִבְּיִבְּיִבְּיִ | 1107701 | a ves | aleva. | | serl seften | mterl |
| 1 | 0 | 15 | 0 | 0 | • | • | 15 | 0 | • | 0 | • | • | 0 | | • | | C | • | C | | • | | · c | • | 0 | • | 6 4 | | 1cular | or covering parts site solid, slevated, hardened, thickening | | ier ei r appl ious e | al res |
| | F | • | 0 | 0 | C | | • | 0 | 0 | 0 | 0 | | | | 0 | 15 | • | 0 | • | | | | | | • | • | Ç | | or b | arden | | plication itrong | Arrelevant to test material reactions |
| | I. | 0 | 0 | 0 | 0 | • | • | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | | 0 | 0 | 0 | 0 | • • | · c | | • | 0 | 0 | i Aour | | ille r | id, th | | tion a on (No test | , t |
| l. | 0 | 0 | 0 | 0 | 0 | , | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | • | | 0 | 0 | 0 | 0 | • | 0 | c | • | • | • | _ | • | eactic | 1cken1 | | fter at the state of the state | į |
| ₹. | E | 0 | 0 | 0 | 0 |) | • | • | 0 | 0 | 0 | 0 | 0 | | • | • | 0 | 0 | 0 | 0 | 0 | 0 | 0 | , | 0 | • | | | - E | 5u | ı | luded lon(s) | |
| : | Z. | 0 | 0 | 0 | 0 | , | • | 0 | 0 | 0 | 0 | 0 | 0 | , | • | | 0 | 0 | 0 | 0 | 0 | 0 | . 0 | | 0 | • | | | - serous exudate - clear | | | Absence Residual reaction to earlier application after absence (Not included in totals) Test patch lost soon after application (Not included in score totals) Patch omitted due to previous strong test reaction(s) Applied to adjacent site because of adhesive reaction or for other reasons | |
| (| 0 | 15 | 0 | 0 | 0 | , | 13 | 0 | 9 | 0 | 0 | 9 | 0 | ı | 0 | 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | | | exudet | | | inclured to the rection of the recti | |
| Chal | < | 13 | 0 | 0 | 0 | ı | 52 | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | • | | | ີ ເ ອ | | | ided in | |
| Challenge | ò | 22 | 0 | 0 | 0 | | 15 | 0 | 0 | 0 | 0 | 0 | 0 | (| • | 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | | | lear Te | | | n tote | |
| | < | 15 | 0 | 0 | 0 | | 15 | 0 | 0 | 0 | 0 | 0 | 0 | • | • | 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | • | | | | | | (914) | |

Individual reaction scores following the application of test material. Sample: C (50% in Mineral Oil 8P-7053 in Finished Oil) Table 1C.

| | • | | 0 | 0 | c | | > | 0 | | c | , | | 0 | 0 | 0 | • | 9 | 0 | 0 | , , | > | | | |
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| 5 | Cuerreud * | • | 0 | 0 | C | | 9 | 0 | | • | • | | 0 | 0 | c | • | 0 | 0 | C | • (| 0 | | | |
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| | | 5 | 0 | 0 | | > | 0 | 0 | 202 | | > | | 0 | | | - | 0 | ¢ | ٠, | - | 0 | , | 100 | |
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| | g=4 | 0 | | 0 | 0 | • | > | 0 | ā | 0 | • | • | • | 0 | 0 | • | > | • | 0 | • | 3 | 0 | - original aite; H | s first scoring of original and adjacent challenge sites (40 hours) |
| | 2000年4回の | Munder | | 16 | 11 | . 6 | B) =4 | 6 | 30 | 2 | i e | 9 (| M | 34 | 60 | 9 (| 9 | G | 6 | 9 6 | N | 0 | 0 | e 4'0 |

- Mild reaction - macular erythems (faint, but definite pink) a No visible reaction and/or erythema

- Moderate reaction - secular erythems (definite redness, similat to a sunburn)

m Strong to savers reaction - macular erythems (very intense reduses)

o Edema - swelling, spongy feeling when palpated

w Vesicles - small elevation containing serous fluid (blister-like), diameter - Payales - red, solid, pinpoint elevations, granular feeling

= Bulla reaction - fluid-filled lesion greater than 0.5cm in diameter = apresding - avidence of the reaction beyond the test site

weeping - result of a vesicular or bulla reaction - serous exudate - clear

Induration - solid, elevated, hardened, thickening fluid coaing or covering patch site

= Hypopigmentation (loss of visible pigmentation at test site) = Fissuring - grooves in the superficial layers of the ekin **72**

- Scab, dried film of serous exudate of vesicular or bulla reaction

 Olazing - Poeling

0

Ayparpigmentation (reddish-brown discoloration of test site)

 Residuel resttion to earlier application after absence (Not included in totals) m Test patch lost soon after application (Not included in score totals)

- Applied to adjacent site because of adhesive reaction or for other reasons - Patch omitted due to previous strong test reaction(s) HXE

irrelevant to test material reactions

 \sim Patch cmitted for reasons unrelated to the test Š

w No minth grade

Table 1C. Group total reaction scores following the application of test material. Sample: C (50% in Mineral Oil 8P-7053 in Finished Oil)

| ecent test | A A SA | • | 11 | | | 9 | 13 13 | e. | 4 6 | | | | | 0 (| | и и | 15 15 | 0 | 0 | | 0 | | 0 | 0 | | 0 | 0 | | 1881 7 | Absence Residual reaction to earlier application after absence (Not included in totals) Test patch lost soon after application (Not included in score totals) Patch omitted due to previous strong test reaction(s) Applied to addacent site because of adhesive reaction or for other reasons | |
|--------------------|---|------------|------------|----------|------------|----------|-------|----------|------------|------------|------------|---------------|------------|------------|------------|---------|------------|--------|------------|------------|---------------|------------|------------|---------------|---|------------------|---|---|--|--|-------------|
| ć | 5 4 | \$; | 7 | > 0 | > | • | 13 | r | v c | • | 9 (| • | 0 (| 0 (| 0 | ~ | 13 | • | • | • | 0 | 0 | 0 | 0 | | 0 | • | | ; 9 | ided :: tals) | |
| | c | · ; | e c | > < | - | 0 | 2 | • | ~ C | • | 0 (| 0 | 0 | • • | 9 | 8 | 15 | c | | 0 | | • | 0 | 0 | | 0 | • | | a vesicular or bulla reaction - serous exudate - clear ering patch site elevated, hardened, thickening | earlier application after absence (Not included in to after application (Not included in score totals) previous atrong test reaction(s) | |
| | = | į (| 0 0 | 9 (| > | 0 | 0 | c | - | 5 (| 0 | 0 | 0 | 0 | 0 | 0 | | c | 0 | • • | · c | C | 0 | 0 | | 0 | 0 | | erous | in ac | |
| Ş | E ■ | E (| 0 (| • | 0 | 0 | 0 | • | > 6 | • | 0 | 0 | 0 | 0 | 0 | • | m | c | • | • | • • |) C | • | 0 | | 0 | • | | - P | ibsenc uded on(s) | |
| | ٥ | • | m (| - | 0 | 0 | М | • | 0 0 | 0 | 0 | 0 | 0 | 0 | 0 | e | | c | , | , | • | • • | • • | 0 | • | 0 | 0 | _ | n reaction thickening | ter a incl | |
| | 12 | 1 | 0 | - | 0 | 0 | 0 | • | 0 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | | c | . | , | • | , | • • | | • | 0 | 0 | second scoring of challenge sites (96 hours) | illa re od, thi | Absence Residual resction to earlier application after absence Test patch lost soon after application (Not included i Patch omitted due to previous strong test reaction(s) applied to addecent site because of adhesive reaction | |
| • | ֓֞֞֞֞֟֞֟֟֓֓֟֟֟֟ ֓֓֞֞֞֞֜֞֞֜֞֞֜֞֞֜֞֜֜֞֜֓֓֞֜֜֡֓֓֓֡֡ | E . | 0 (| 0 | 0 | Э | 0 | • | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 13 | • | > < | > < | • | > < | · c | | • | 0 | • | 96) 8 | or bu ite rdene | 11cat catic rong | 1 |
| | ١ | • | = (| 0 | 0 | 0 | 11 | • | ٠, | - | 0 | 64 | 0 | 0 | 0 | 4 | | • | | > < | > 0 | > 0 | , | · c | • | 0 | 0 | site | ular tch s d, ha | r app app14 us et | |
| | : | Į | 0 1 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | • | . | > 0 | > 0 | > 0 | ۰ د | • | • | 0 | 0 | l Jenge | Weeping - result of a vesicular or bulls fluid cozing or covering patch site Induration - solid, elevated, hardened, | earlia eftor previc | |
| • | ا د | Ε | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | • | o 0 | o 0 | > (| 5 6 | . | • | > | ٥ | • | chel | g g g | n to (| |
| | 1, | 0 | 12 | 0 | 0 | 0 | 12 | | - | 0 | 7 | 0 | 0 | 0 | 0 | m | | • | 0 0 | 0 | ٠ د | 5 (| > 0 | • | > | 0 | ٥ | ing of | esult ig or c soli | action lost i ed du | 1 |
| | : | Ę | 0 | 0 | 0 | 0 | 0 | , | 0 | 0 | 0 | 0 | 0 | 0 | ٥ | 0 | | • | 0 (| 0 (| 0 | 0 1 | . | > 0 | > | 0 | 0 | 800 | Weeping - result fluid cozing or c Induration - soli | Absence Residual reaction to Test patch lost soon Patch omitted due to Apolied to addacent s | 3 |
| ı | -¦: | E; | 0 | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | | 0 | 0 (| 0 | 0 | 0 0 | 5 6 | > | 0 | 0 | second | Weeping - 1 fluid cozir Induration | Absence Residua Test pa Patch o | on parrddu |
| | | 0 | 14 | 0 | 0 | 0 | 14 | ; | - | 0 | 0 | 0 | 0 | 0 | 0 | ~ | | | 0 | 0 (| 0 | 0 | o (| > • | > | 0 | • | 8 | 1 I | | 8 |
| umber | 1 | £ | 0 | 0 | 0 | 0 | c | , | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | • | 0 | 0 | 0 | 0 (| 0 (| 0 | 0 | 0 | O', A' | | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | • |
| ton M | 1 | E | 0 | 0 | 0 | 0 | c | , | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | | 0 | 0 | 0 | 0 | 0 | 0 1 | 0 | 0 | 0 | | aunburn) | 6 6 74 | |
| Application Mumber | | 0 | 13 | 0 | 0 | 0 | - | 3 | ed | 0 | 0 | eri | 0 | 0 | 0 | 8 | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | like), diameter | |
| Apj | 1 | Z | • | 0 | 0 | 0 | - | • | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | e | site uxs) | it to | lke), | |
| | 1 | E | 0 | 0 | 0 | 0 | c | • | 0 | 0 | 0 | 0 | 0 | | 0 | ٥ | 15 | | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 0 | oved s | nk) simile | | |
| | | 0 | 13 | 0 | 0 | 0 | Ş | 7 | 0 | 0 | ~ | 0 | | | 0 | n | | | 0 | c | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - second moved ge sites (40 h | te pis sss, i | feel (b11s | |
| | 1 | H | 0 | 0 | 0 | | • | - | 0 | 0 | | | | | . 0 | 0 | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1000 | efini redn | nular Inda | |
| | | z | 0 | 0 | 0 | | | • | 0 | 0 | · c | , c |) c |) c | | • | 15 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | 11 12 13 19 11 | but d | pated , gr | |
| | | 0 | 14 | 0 | · c | . 0 | | * | 0 | | , c | , c |) C | > ~ | 4 0 | - | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | ite; M mt ch | lat, (dei | ation | |
| <u> </u> | , | MI | 0 | 0 | | | | 9 | 0 | · e | | | , | , | | | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | original site; $M \to first moved site; M1 \to second moved site$ | Mo visible reaction and/or erythems Mid reaction - macular erythems (faint, but definite pink) Moderate reaction - macular erythems (definite redness, similat to a Arreas to severe reaction - macular erythems (very intense redness) | Edema - swelling, spongy feeling when palpated Papules - red, solid, pinpoint elevations, granular feeling Vestoles - smell elevation containing serous fluid (blister- | |
| | 6 | 1 | 0 | | | . 0 | , , | 0 | 0 | , c | | , | , | . | , c | | 15 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | at mo | r ery rythe er er | feel1 point n con | |
| | | ٥ | en en | | , | | • 1 | 5 | c | ~ | > c | . |) | . | | | *** | - | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | e fir | and/o | ongy I, pin | |
| | | ľ | | | | | | 9 | c |) C | , | > (| > 0 | 9 (| . | | | | 6 | 0 | 0 | 0 | 0 | 0 | 0 | • | • | A Ort | rtion Francia | 19, 91 90114 | |
| | N | i | | | | | | | c | | | | | | | | 6 5 | 4 | 0 | 0 | | | | | 0 | ٥ | • | ite; ing o | for the state of t | 701111 70 4, | 2 |
| | | | £ | | | | | 20 | | | | | | | | | | | | | | | | | | | | e oxiginal site; M e firet ecoring of | Mo visible reaction and/or erythema Mid reaction - mecular erythema (f) Moderate reaction - macular erythem mercan to assers reaction - macular erythem | | Sam or Jose |
| 9 | • | . 0 | * | 9 6 |) (|) C | • | 7 | c | > 6 |) | 9 (| 9 (| 9 • | P4 (| > 4 | e. | 7 4 | 0 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | or 191 | | | |
| | | Scores | 6 | . | = (| ~ ~ | 3 | Total | | dora | 2 | | e : | ×. | a ş | Total A | Grand | * | 36 | B | | | | 3 | Þ | Latter Totals | æ | 9 8 | 9 6 3 5 | | |

s Mo minth grade

Table 1A. Individual reaction scores following the application of test material. Sample: A (MINERAL OIL)

| | uj | Sampie: A (Minakum Uli) | verl v | | 3 | | | | | | | 1 | annitration Mushar | red red | | | | | | | | | | | | |
|----------------|--------|--|---------|--|--------------|------------------|---|--------------|-------------------|-------------|--------------|----------------|--------------------|---------------|---|------------|---------------|---|---------------|------------------------|------------------|---|----------|------------|---------------|----------|
| e e e e | ė | - | ~ | | (4) | | | 4 | | | S | | 9 | · 1 | | | | | | - 1 | 1 | 1 | | Challenge | ebue | |
| Number | | 10 | 1 | 0 | E | M | 0 | | E | o | M M1 | 0 | E | M | E . | M1 | 0 | E | 0 | E E | 0 | W W | 0 | 4 | ò | <u>.</u> |
| t _e | | 0 | - | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | • | | | | 2 | 0 | | 0 |
| 4 C | | | | 0 | | | 9 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | 0 | 0 | 0 | 0 |
| 9 6 | | | | 0 | | | 9 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | • | . | • | 9 |
| 9 69 | | | | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | 0 (| o (| ۰ ، | |
| 1 E | | 0 | | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | 9 (| . | ۰ د | |
| 8 | | | | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | 9 | • | 0 | • |
| 9 6 | | | | 0 | | | • | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | 0 | | 0 | 0 | ۰ ، | 0 |
| 9 6 | | | | 0 | | | 0 | | | 0 | | 0 | | _ | | | 0 | | | | ę | | 0 | 0 | ۰ ، | ۰. |
| (A) | | | | • | | | 0 | | | 0 | | 0 | | _ | ۵ | | 0 | | 0 | | | | 9 | • | 0 | 0 |
| 4 | | | Dropped | ~· | | | | | | | | | | | | | | | | | | | • | • | • | • |
| ** | | | | 0 | | | 0 | | | 0 | | • | | _ | 0 | | 0 | | 0 | | | | 0 0 | 5 6 | > • | > 0 |
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| * ** | | | | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | ۰ د | 5 (| 5 (| . |
| 9 4 | | | | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | 0 | . | . | . |
| 9 4 | | - | | · C | | | a | | | 4 | | O. | | _ | 0 | | 0 | | • | | 0 | | 0 | 0 | . | |
| 9 4 | | - | | • | | | • | | | 0 | | 0 | | _ | 0 | | 0 | | 0 | | | | 0 | 0 | 8 | |
| 9 9 | | | |) C | | | · c | | | | | 0 | | _ | 0 | | 0 | | 0 | | | | 0 | 0 | 0 | 0 |
| 9 | | | | > < | | | • | | | | | · c | | | 0 | | 1 | | 0 | | 0 | | 0 | 0 | 0 | 0 |
| | | | _ | > (| | | > 6 | | | > < | | • | | _ | | | • | | c | | | | 0 | 0 | 0 | 0 |
| 9 | | | _ | 0 | | | 9 | | | . | | > 0 | | | | | • • | | • • | | | | 0 | 0 | 0 | 0 |
| 0 | | 0 | _ | 0 | | | 0 | | | o , | | > | | | • | | > | | • | | | | | | | |
| (대 왕) | | | | 0 | | | 0 | | | Dropped | T a | • | | | | | • | | • | | | | 0 | 0 | 0 | 0 |
| 69 69 | | | _ | 0 | | | 0 | | | 0 | | - | | - | | | ه د | | ۰ د | | | | • | 0 | 0 | 0 |
| 6 1 | | 0 | _ | • | | | 0 | | | 0 | | 0 | | • | 9 (| | 5 6 | | > < | | | | • • | | | 0 |
| 80 | | 0 | _ | 0 | | | 0 | | | 0 | | 0 | | | | | > (| | > 0 | | | | | | | |
| 8 1 | | 0 | _ | 0 | | | 0 | | | 0 | | 0 | | - | | | > 0 | | > f | | | | | 0 | 0 | 0 |
| 9 | | 0 | _ | 0 | | | 0 | | | 0 | | 0 | | | 0 | | - : | | > 6 | | • | | . c | | | 0 |
| 23 | | 0 | _ | 0 | | | 0 | | | 0 | | 0 | | • | | | 0 | | 5 ; | | > 0 | | | | | |
| (F) | | 0 | _ | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | : | | · · | | > | | | | | |
| 8) (1) | | 0 | - | 0 | | | 0 | | | 0 | | 0 | | _ | 0 | | 0 | | o ! | | • | | , | • • | | |
| 09 | | | _ | 0 | | | 0 | • | _ | 0 | | 0 | | | 0 | | 1 | | 0 | | 0 | | > | > | • | , |
| 1 | | | : | | 1 | • | | | | | 440 | | | | | | | | | | | | | | | |
| 4 0 0 | 2 O719 | original site; M = tirst moved site; Mi = second moved site first ecoring of original and adjacent challenge sites (40 hours) | No Bu | origine | iret 1 er | Moved 1d adja | kirst moved sits; mi .nal and adjacent cha | 11 1811en | - 60Ct 198 811 | sates (40 h | hours) | | | ٥, ١٧, | 000000000000000000000000000000000000000 | nd scor | ing of | second scoring of challenge sites (96 hours) | sites (| 96 hours | _ | | | | | |
| • | 0 | Mo vielble reaction and/or erythems | 2000 | /pue mo | or | ryther | • | | | | | | | 5 | = Olazing | Ing | | | | | | | | | | |
|) =4 | | Mild reaction - macular erythema (faint, but definite pink) | 50 | acular. | | thema (| faint, | but | 10£1n11 | a pink | _ | | | | - Peeling | ing | | | | | , | ; | 1 | | | |
| · 68 | | Moderate reaction - macular erythema (definite redness, similat to a sunburn) | action | | lar | orythe | (Q0) em | tinite | redn | 188, 81 | milet t | o a su | nparu) | | a Scab | , dried | film o | g serons | exudate | of vestor | ular or | scab, dried film of serous exudate of vesicular or bulla reaction | action | | | |
| (T) | | Strong to severe reaction - mecular erythema (very intense redness) | SVOI O | rescti | F | macu] | r eryt | hema (| VOLY | ntense | rednes | <u> </u> | | - | | rpigmen | tation | (reddish- | brown di | scolorat. | lon of | Hyperpigmentation (reddish-brown discoloration of test site) | | | | |
| 8 | | | 9 | | | | | | _ | | | | | z • | a Hypo | pigment | ation (| Hypopigmentation (loss of Visible pigmentation at Elements and an element of t | annerfic | igmentet. im lave | | the skin | | | | |
| M (| | Ecomo — evelling, spongy leeling when palpared | Beerg. | · apond. |) Ke | aling k | nen pa | lpeted | | - P (0 | | | | | | . Guran | | | | | | | | | | |
| . > | | | 9231 | - 1947, Wolley, Pingolnic Widestone, Wienuidel Leviling - 1988 1988 Oliver Containing Berone fluid (Dileter | | contain | Ang se | rone a | | bliste | y r-11ko) | ike), diameter | ater | 1 | - Absence | ມດອ | | | | | | | | | | - |
| | | Sam or less | | | | | 1 | | | | • | | | 42 | s Resi | duel re | action | to earlie | r applic | ation af | ter abs | Residual resction to earlier application after absence (Not included in totals) | includ | מו פו | | |
| | | Mulla reaction - fluid-filled lesion greater than 0.5cm in diameter | .10m - | Lluid- | 1111 | ed lesi | on gre | ster t | han 0. | Scm in | diamet | 20 | | | | patch | lost so | on after | applicat | 10n (Not | 107100 107100 | Test patch lost soon after application (Not included in score comments) | | | | |
| m 3 | | Spreading - evidence of the reaction beyond the test site | · evid | ance of | the | reacti | on bey | ond th | 882 | . site | • | , | ! | × 6 | s Pate | h omitt | :@d | Patch caitted due to previous strong test sections: | nos stron | g temet ke Adhemiye | a react | Patch caitted due to previous attong test section;; , | r other | ressor | e | |
| B | | weeping - tessic of a Vesicular of bulls rescrion - serous ex flaid coxins of covering batch site | TERRAL | or a v. | a pat | LCh sit | errna e | | E E E | | | Loste - Clear | * | 4 | | Appiles to | to test | test material reactions | reaction | 90 | | | | | | |
| M | 134 | Induration - | - 8011 | solid, elevated, hardened, thickening | rate. | d, here | ened, | thicke | nang | | | | | ğ | . Pate | h omitt | ed for | Patch caitted for reasons unrelated to the test | nrelated | to the | test | | | | | |
| | | | | | | | | | , | | | | | | | | | | | | | | | | | |

Table 1A. Individual reaction scores following the application of test material. Sample: A (MINERAL OIL)

| Subject Mumber | ñ 8 7 7 | ~ 0 | 70 | lo I× | M H1 | 0 | M M1 | 0 | A M1 | plicat | Application Number 6 6 H H1 | io io | ~ = | F | 0 | 6 M M1 | 9 M | Æ | S. Z. | E . | ۰ | Challenge A O' | eg. | ` ~ |
|-------------------|----------------------------|--|--|-----------|---|-----------|----------------------|-----------------------|-----------|-------------|-----------------------------|---------------|-----|---------------------|--------------------|--|--|--------------------|-------------------|------------------------------------|---------------|-------------------|-------------|---------------|
| 5 | | 0 | 0 | 0 | | 0 | | ı | | o O | | 0 | _ | | 0 | | 0 | | 06N | | 0 | 0 | 0 | • |
| 8 | | 0 | 0 | 0 | | 0 | | 0 | | 0 | | • | _ | | 0 | | 0 | | | | 0 | 0 | 0 | 0 |
| F | _ | 0 | 0 | 1 | | ů | | 0 | | 0 | | 0 | _ | | 0 | | 0 | | 0 | | 0 | 0 | 0 | 0 |
| 79 | | 0 | 0 | 0 | | 0 (| | 0 (| | 0 6 | | 0 | | | 0 0 | | 0 6 | | | | 0 (| ۰ د | 0 (| . |
| 69 E | | 9 6 | 9 6 | 0 6 | | - | | - c | | - | | 5 C | | | > 0 | | - - | | | | - | | o c | 5 C |
| 9 4 | • | Dropped |) E | > | | • | | • | | • | | • | | | , | | • | | | | • | > | • | • |
| 9 | | | 0 | 0 | | • | | | | 0 | | • | _ | | 0 | | 0 | | Dropped | _ | | | | |
| 9 | | 0 | 0 | ô | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | III | | 0 | 0 | 0 | 0 |
| 70 | | 0 | 0 | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | | | 0 | • | 9 | 0 |
| 71 | | 0 | 0 | 0 | | Dropped | e T | , | | , | | , | | | (| | , | | | | • | | | |
| 12 | | 9 (| 0 0 | 9 6 | | 9 6 | | 5 C | | 5 C | | > c | | | . | | . | | | | , | , | > | , |
| , L | _ |) |) C | 9 6 | | , | | | | | | • | | | • 0 | | | | | | . 0 | 0 | . 0 | |
| | |) C | | • • | | | | . 0 | | 0 | | 0 | | | 0 | | • | | | | 0 | 0 | | |
| | | ේ ර | | • | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | | | 0 | 0 | 0 | 0 |
| 6 | | | • • | 0 | | • | | 0 | | 0 | | 0 | | | 0 | | • | | | | 0 | 0 | 0 | 0 |
| 78 | | 0 | 0 | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | | | 0 | 0 | 0 | 0 |
| 79 | _ | 9 | 0 | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | | | 0 | 0 | • | |
| 8 | _ | 0 | 0 | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | | | 0 | 0 | • | 0 |
| | | Dropped | | | | | | | | | | | | | | | | | | | | | | |
| 8 | | 0 | 0 | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 | | | | 0 | ۰, | | ۰ ۵ |
| 8 | | 0 | • | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | 0 1 | | | | . | . | | > 6 |
| * | | • | . | 0 | | 0 | | 0 | | 0 | | 0 | | | 0 | | o (| | | | > • | > | | . |
| | | 9 (| 9 (| 9 (| | Θ (| | o (| | o (| | 0 (| | | ۰ ، | | ٥ (| | | | - | | > < | |
| | | o | 9 | 9 | | 0 | | 0 | | - | | 0 | | | 0 | | o : | | | | > (| > 0 | | > 6 |
| | | 9 | 0 | 0 | | 0 | | 0 | | 0 | | 0 | | | | | 0 | | 0 | | 0 | 0 | | 5 |
| 0 (| | ginel | original alta; M | 8 | " first moved alte; Mi | alte, Hl | 3 | · m second moved site | d site | | • | | | • | • | | | • | | | | | | |
| Ę. | 14 14 16 16 18 | 7 2 2 | icano de la como de la | origin | tiret ecoring of original and adjacent challenge sites (48 hours) | cent cha | llenge si | 89: 84 | hours) | | 0 | , k, 'O | | acozir | ig of ci | allenge e | second scoxing of challenge sites (96 hours) | onza) | | | | | | |
| • | | visibl | o react | Jon and, | No visible reaction and/or erythems | 9 | | | | | | 5 | | 5 | | | | | | | | | | |
| e-6 (| | u Kobi | tion - | mecular. | Mild reaction - macular erythema (faint, but definite pink) | (faint, b | ut defini | e pink) | | | | * | | <u>g</u> | | | | | | | : | | | |
| 60 F7 | | erate one te | resctic | W - Baci | Moderate reaction - macular erythema (definite redness, similat Strong to severe reaction - macular erythema (very intensa redna | ma (defi | nite redn | os, siz eteres | to E | a sunburn) | ırn) | 0 7 | | dried (| tim of | serous ex | Scab, dried film of serous exudate of vesicular or bulla rea Hyperpiquentation (reddish-brown discoloration of test site) | esicula oration | r or bu of tes | or bulla reaction of test site) | tion | | | |
| 1 | 1 | i N | | | | | F40 | | | | | | | gmentat | ton (1c | as of vis | Hypopigmentation (loss of visible pigmentation at test site) | ntation | at tes | t site) | | | | |
| 96 (| | | volling | 's spong. | Edema - awelling, spongy feeling when palpated | then palp | at@d | | | | | \$ \$4 | | dng - g | - grooves in | in the ev | the superficial layers of the akin | layers | of the | skin | | | | |
| > > | | 1030 | red, s | olid, p: | Papules - red, solid, pinpoint elevations, granular feeling Vestoles - essil elevation containin escone dud divisoration dissert | wations, | granular na eleta | feeling hitetor | 24801 | e e e e e e | 9 | | | | | | | | | | | | | |
| • | | Sam or less | | | | ozee fur: | | TO TECHT | -41KB), (| 17 amo te | <u>La</u> | | | | +400 | eerl ter | Absence Bestdus 1 resettes to earlier application after absence (Not included in totals) | n after | | a (Not 1 | nc lude | 1 in t | otals | _ |
| | | le red | etion - | fluid-i | Balla reaction - fluid-filled lesion greater than 0.5cm in diameter | lon great | er than 0 | Sca in | diameter | | | | | atch 1c | st soon | after ap | Test patch lost soon after application (Not included in score totals) | (Not in | cluded | in score | total | - | | |
| • 3 | | oedini Mar | - 6724 | lence of | Spreading - evidence of the reaction beyond the test site | lon beyon | d the tes | . site | | | | K (| | omitted | due to | previous | Patch omitted due to previous strong test reaction(s) | at reac | tion(s) | 8 6 | 400 | | • | |
| : | | 14 602 | ing or | covering | Iluid cosing or covering patch alte | | | | | | | 5 | | ra to ma Went to | jacent , test m | hppised to adjacent site pecause of a Arrelevant to test material resotions | sactions | | | | | | | |
| b=6 | | sett. | a - 80] | id, ele | Induration - solld, elevated, hardened, thickening | dened, th | tckening | | | | | Ş | | omitted | for re | ssons uni | Patch omitted for reasons unrelated to the test | the tee | נג | | | | | |
| | 9 | ### ################################## | ar a da | | | | | | | | | | | | | | | | | | | | | |
| 9 | | 200 | | | | | | | | | | | | | | | | | | | | | | |

Table 1A. Individual reaction scores following the application of test material. Sample: A (MINERAL OIL)

1990 - No minth grade

Table 1A. Individual reaction scores following the application of test material. Sample: A (MINERAL OIL)

| 800 |), A | 0 | | 0 | | | | | | | | 0 | | 0 | 0 | | | | 0 | 0 | | | | gecond scoring of challenge sites (96 hours) Glasing Peeling Peeling Beab, dried film of serous exudate of vesicular or bulla reaction Ryperjdgmentation (reddish-brown discoloration of test site) Bypoplgmentation (loss of visible pigmentation at test site) Bypoplgmentation (loss of visible pigmentation at test site) Fissuring - grooves in the superficial layers of the skin Absence Residual reaction to earlier application after absence (Not included in totals) Test patch lost soon after application (Not included in score totals) Applied to adjecent site because of adhesive reaction(s) Applied to adjecent site because of adhesive reaction or for other reasons irrelevant to test material reactions Patch omitted for reasons unrelated to the test |
|-------------------------|--------------|---|---------|-----|----------|---|----|---------|---|---|-----|------|---------|--------|----------|---------|---|------------------|----------------|----|---------|---|-----|--|
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| | H1 | | | | | | | | | | | | | | | | | | | | | | | a se mude e defin defin forty vd (Very vd than than than itlon itl |
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Table 1A. Group total reaction scores following the application of test material. Sample: A (MINERAL OIL)

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| 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | | - | 0 | 0 | 0 | | 0 | | • | 0 | 0 | 0 |
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Table 18. Individual reaction scores following the application of test material. Sample: B $(SP-7053\ {
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Table 18. Individual reaction scores following the application of test material. Sample: 8 (82-705) in Pinished Oil)

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| | lo | 0 | 0 | 0 | 0 | 0 | 0. | 0 | 0 | 0 | | 0 | 0 | 0 | Dro | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | # first moved site; Miginal and edjacent cha | | alnt, eryth en pal ettons ations ng sex n grea n beyo | |
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| 60 | E | | | | | | | | | | | | | | | | | | | | | | | | | | | | at mo | | rery rythe rythe rest rest rest recon recon recon recon recon recon recon recon recon recon recon recon recon recon | |
| | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | ٥ | 0 | | 0 | 0 | 0 | ۰ د | o (| 0 | 0 | 9 | 0 | 0 | 0 | ~ | 0 | , | 0 | 0 | 0 | original site; M = first moved site; M1 = second moved site first ecoring of original and adjacent challenge sites (48 hours) | | Moderate reaction and/or exythema (faint, but definite pink) Moderate reaction - macular arythema (faint, but definite pink) Moderate reaction - macular arythema (definite redness, similar to a sunbustion of the section - macular exythema (very intense redness) Edema - swelling, spongy feeling when palpated Papules - smell elevation containing serous fluid (blister-like), diameted Smm or less Smm or less Small elevation containing serous fluid (blister-like), diameted Small elevation - fluid-filled lesion greater than 0.5cm in diameter Meaping - result of a vesicular or bulla reaction - serous exudate - clear fluid cozing or covering patch site Induration - solid, elevated, hardened, thickening | |
| | I. | | | | | | | | | | | | | | | | | | | | | | | | | | | | Z OZ | | 100 - | |
| ~ | lo | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | D | 0 | 0 | ο (| 3 (| D (| D | 9 | 0 | 0 | 0 | 0 | eri (| ۰ - | . | > • | 9 | 0 | ileg ing (| • | rescui rescui rescui rescui rescui rescui rescui rescui rescui rescui | |
| + | 10 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | Dropped | 0 (| 0 | | . | 5) 4 | ó, | 9 | a | , | 0 | 0 | | | Dropped | _ | | _ | original alte; M first ecoring of | | Moderate reaction Moderate react Strong to seve Edems - svelid Papules - red, Vesicles - sms Smm or less Bulls reaction Spreading - ev Mesping - resu Mesping - resu Induration - s | 1 |
| | | | | _ | _ | _ | - | - | _ | ~ | | - ' | - ' | - ' | - (| - • | ا سے | | . | • | ~ | _ | 0 (| 9 (| - 3 € | 9 (| 9 | 4 | origi first | | Moder Mild Moder Edema Pepula Pepula Peres Peres Iluid Indur | |
| # # # # # | Nadari. | 89 | 60 | 60 | 63 | 62 | 6 | 99 | ଞ | 19 | 6 | න (මේ (| 90 (160 (| 2 : | 7 6 | 2 6 | E (| 9/ | 13 | 2 | ا حيا ا حيا | e | P | | =4 (B) (| *** | 9) · | 50 50 | | | | |

Table 18. Individual reaction scores following the application of test material. Sample: B (SP-7053 in Finished Oil)

| ## 15 | Application Number Miles C | Application Number Miles C | MI MULLIPET IN THE PARTY OF THE |
|--|--|---|--|
| M1 d site hours | M1 d site hours) 11st fredner cannot redner diame | M1 d site hours) 11st fredner cannot redner diame | M1 d site hours |
| atte; M1 = aecond moved sacent challenge sites (48 house when palpated every intense red wattom greater than 0.5cm in discussion beyond the test site expense con the control of the contr | 3 | 2 | 1 |
| atte; M1 = acent challeng as expthema (v when palpated avations, granning as excus filling as exetted filling fi | a Marking as a macular exythema (verthema (verthema (definite) and definite and def | 2 H O H HI O H H H H H H H H H H H H H H | 1 |
| | 3 0 M M1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | o H O H MI O O O O O O O O O O O O O O O O O O O | 1 |

Table 1B. Individual reaction scores following the application of test material. Sample: B (SP-7053 in Finished Oil)

| | MI O A O' A' | 0 0 0 | 0 0 0 0 | 0 | | | 0 | 0 | 0 | 0 0 0 | | 0 | 0 | 0 | | ropped | 0 | 0 0 0 | 1 | 0 | 0 | 0 | | copped | 0 0 0 | 0 | | | | Scab, dried film of serous exudate of vestcular or bulla reaction | test site) | test site) | BAAII | | Absence | Residual rescribt to estiler application sites species (not andrus) co | | Fatch omitted due to previous strong test rection or for other reasons | | | | |
|--------------------|-------------------|-------|---------|-----|---|---------|----------|----------|-----|--------|---------|-----|-----|-----|----|--------|-----|--------|----------------|-----|------------|----------|----|--------|---------|-----|---|-------------------------------------|---|---|---|--|--|---|---|--|--|---|---------------------------------------|--|----------------|---|
| 5 | E | | | | | | | ô | | | | | | | | | 0 | 0 | | | 800 | | | | | | | | | ar or bu | n of tem | ٠. • | Of the BAAR | | 1 | r epecification | offon(a) | reaction | | u و | | |
| | M | | | | | | | | | | | | | | | | | | | | | | | | | | hours) | | | vesicul | oloratio | mentatio | T TENER | | 40 m - F | TOU STEE | test res | dhestve | | o the te | | |
| G | 0 | 0 | 0 | 0 | 0 | | 0 | | ٥ | 0 | | 0 | 0 | 20G | 0 | 0 | Ç | 0 | | 0 | 0 | 0 | 0 | 26M | 0 | 0 | second scoring of challenge sites (96 hours) | | | rudate of | Hyperpigmentation (reddish-brown discoloration of | Hypopigmentation (loss of visible pigmentation | Fissuring - grooves in the superincial layers of | | 40.00 | appiacat | Josef Daffer Josef Boom Bires spyllication (Not American Books and seed American services services the Post Topolical | mass of a | irrelevant to test material reactions | Patch cmitted for reasons unrelated to the test | | |
| | M | | | | | | | | | | | | | | | | | | | | | | | | | | illenge # | | | erone ex | ddish-br | SE OF VAR | in the su | | | GETITEL | dream appear | PASSACE 14te Dece | terial r | seone unz | | |
| a | 0 | 0 | ٥ | 0 | 0 | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | | 0 | | 0 | • | 0 | 0 | 0 | 0 | ٥ | ng of che | | | film of a | ation (re | tion (lo | grooves 1 | | 1 1 1 | ction to | noon year | d cus to | o test m | d for res | | |
| | M | | | | | | | | | | | | | | | | | | | | | | | | | | nd scort | 5 | ing ing | dried, | rpigment | pigmenta | uring - (| | 900 | dual read | parcu 1 | 4 64 48 A | levent to | h caitte | | |
| | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 50.50 | 8 | 8 | Ð | 8 | 8 | | 8 | 8 | 9 8 | | 1 | • | | |
| Number | M1 | | | | | | | | | | | | | | | | | | | | | | | | | | 0', A' | ε | n >- | | | £ ' | ₽₩ | | | e . | 3 > | < 6 | 6 | Ħ | | |
| Application Number | E . | 0 | 6 | 0 | 0 | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | • | Dropped | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | at to a sunburn) | | | | | ameter | | | # @ @ F | 8 | | | |
| App | Æ | | | | | | | | | | | | | | | | | | | | | | | | | | site ours) | | | at to a | dness) | | | | jke), diameter | 4 | and cor | ogtertang – evidence of che featisten beyond the test site Wessign – result of a vesimilar or bulla searthon – earns syndete – rlear | | | | |
| el | E 0 | | | _ | _ | | _ | _ | _ | _ | | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | moved (48 hc | | pink) | , simil | ense re | | | eling | inter-1 | 44 44 | | Jen Pane | | | | |
| | ¥ | 0 | | 0 | 0 | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | • | 0 | 0 | | 9 | 0 | 0 | 0 | 0 | 0 | • | 0 | = second moved ge sites (48 h | | stinite | redness | rery int | | | mlar fe | luld (bl | 6 | oc.ocuration | o twee e | | ılng | | |
| • | , E | | | | | | | | | | | | | | | | | | | | | | | | | | Ml . | • | , but de | 11111to | thema (v | , | 1pated | ns, gran | rons K. | 100 | Bater ti | fond the | | thicker | | |
| | 0 | o | 0 | 0 | • | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | first moved site; Minal and adjacent cha | | (Kaint | hema (d | lar ery | | when p | levatio | ining s | - | TO HOTE | Cause De | 140 | rdened, | | |
| | M MI | | | | | | | | | | pad | | | | | | | | | | | | | | | | and ad | a searth. | rythems | ar eryt | - 2000 | , | reeling | point a | a conta | 9 | Days | le tem | patch a | ted, ha | | |
| | 0 | c | | · c | • | | 0 | 0 | 0 | ~ 0 | Dropped | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | riginal | | cular e | - macul | saction | | Boongy | id, pin | lovatlo | 2 A A 6 8 | 4430-13. | 10 | vering | , eleva | | |
| • | Z Z | _ | | | | Dropped | la la | _ | _ | _ | | _ | | _ | _ | _ | _ | _ | _ | | _ | | _ | _ | - | _ | original site; M = first moved site; M1 = second first scoring of original and adjacent challenge sites | smedtyre volkes actores at the same | Mild reaction - macular erythema (faint, but definite pink) | Moderate reaction - macular enythema (definite redness, simil | Strong to savere reaction - macular erythems (very intense redness) | į | Edema - swalling, spongy feeling when palpated | Papules - red, solid, pinpoint elevations, granular feeling | Vesicles - small elevation containing serous fluid (blister-) | observation of John Philips Sanda Catalons Sandan managem (1920 M.S. S. | Bells lostings - Livin-1111ed losion greater than 0.50m l Especialism - moldeson of the seritim house the teat of the | | flaid cosing or covering patch site | Induration - solid, elevated, hardened, thickening | 900 | |
| | 10 ~ 0 | 6 | | | | | 0 | 0 | 0 | TO O | | 0 | 0 | 0 | 0 | 9 | 0.0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | original site; M first scoring of | 4 | rescti | rate re | ng to s | | | 100 | cles . | Dans of Lease | s restra | - See - See | 0021 | ration | Wo minth grade |) |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 20 80 | | a Mode | e Stro | | | | | | | _ | | e Indu | | |
| | aubject Number | 6 | 4 4 6 | 9 6 | | 9 5 | 117 | @ F | 113 | 220 | 121 | 122 | 123 | 124 | 23 | 82 | 223 | 128 | 64 63 69 | 330 | 6 | es es | 64 | 136 | 60 F | 300 | 00 | € |) (P) | 84 | m | (| P4 | 6 1 | > | | 9 6 | 1 2 | : | 1 =0 | | |

Table 18. Group total reaction scores following the application of test material. Sample: 8 (SP-7053 in Finished Oil)

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| Œ | M M1 | 0.6 | | | | 0 | | 0 6 | | | | | | uo. | | | | | | 0 | | 6 | | 0 | halle | a ve axing elev | | n eat | o pre | mater | |
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| | lo | 80 | ~ c | 0 | | 90 | 7 | 0 | ~ | 1 6 | • • | 00 | 10 | | • | 9 | 0 0 | , | 0 | 0 | 0 | c | > | 0 | e fi | alar Wast | 1 | A, po | Svat | 11d-6 | |
| | Z | 0 | 9 0 | | | 0 | 0 | 0 | 0 0 | • | • • | 0 0 | , | | | 9 (| > (|) C | | 0 | 0 | c | > | 0 | D K OX | ion i | | 100 | 11 01 | ion - fluid-filled lesion greater than 0.5cm is evidence of the reaction beyond the test site | _ |
| • | , | 9 | - - | | | 93 | 9 | 0 | en 6 |) | , o | 0 6 | 9 | 5 | 4 | 9 (| ə 6 |) C | | • | 0 | ¢ | > | 0 | site) ring | rescr rescr | PARA | real, | | \$ 5 _ \$ 5 | 6 |
| | - 0 | 60 60 | 0 6 | | | 8 | 64 | 0 | ~ C |) (|) (N | 0 6 | · • | · · · | 3 6 | 9 (| 96 | , | | • | 0 | • | • | 0 | original site; M = first moved site; M1 = second moved site first ecoring of original and adjacent challenge sites (48 hours) | We visible reaction and/or erythems Mid reaction - macular erythems (faint, but definite pink) Moderate reaction - macular erythems (definite redness, simil | ellung tu bevele koncilum - megelek erythema (very intense kedness) | Edema - avelling, spongy feeling when palpated Papules - red, solid, pinpoint elevations, granular feeling | Vesisles - small alevation containing serous fluid (blister-1 5mm or less | Bulla rest con - fluid-filled lesion greater than 0.5cm in di Spreading evidence of the reaction beyond the test site | No alath grade |
| · | | 6 | | | | | | | • | | | | | 25 | | | _ | | | _ | _ | | | | | | | | | | |
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APPENDIX II

(Total number of pages = 1)

Deviations

The following is a list of deviations concerning the length of time the patch was in contact with the skin:

| Subject Number | Application Number | Test Article | Approximate Hours of Contact |
|-------------------|-----------------------|-----------------|------------------------------|
| 9 | 1 | A,B | 9 |
| 20 | 1 | A,C | 22 |
| 87 | 1 | Α | 12 |
| 87 | 1 | В | 4 |
| 120 | 1 | A,B | 5.50 |
| 30 | 2 | A | Unknown |
| 110 | 2 | A,C | 29 |
| 20 | 4 | С | 22 |
| 14 | 5 | A,B | 40 |

Subject Nos. 21, 61, 97, 131, and 134 received nine induction applications, but only eight skin evaluations.

Due to technician error, Subject No. 127 did not have second pregnancy test on October 3, 1994.

Due to technician error, Documentation of Non-Pregnancy was not written down on October 3, 1994. The test results were verified on the following day from the urine and the test kits. The results were recorded at this time.

APPENDIX III

(Total number of pages = 1)

Subjects Failing to Complete

Those subjects who did not complete the study and the reasons why are listed below:

| Subject Number | Reason |
|------------------------|-----------------------------------|
| 21 | Child hospitalized |
| 23 | Work schedule changed |
| 40, 106, 108 | Failed to return |
| 51, 105, 116, 121, 129 | Missed two induction applications |
| 67 | No transportation |
| 68 | Pregnant |
| 71 | Went back to school |
| 81 | Got a job |
| 98, 126, 134 | Missed challenge application |
| 97, 104 | Missed challenge evaluation |

APPENDIX IV

(Total number of pages =1)

Institutional Review Board Approval

INSTITUTIONAL REVIEW BOARD

OF

PROJ. No. PAGE No.

HILL TOP RESEARCH, INC.

Robert H. McMaster, M.D., Chairman

July 12, 1994

Robert A. Harper, Ph.D. Hill Top Research, Inc. Main and Mill Streets Miamiville, OH 45147

Ref:

94-1399-70

Title:

REPEATED INSULT PATCH TEST WITH

(Modified Draize Procedure)

Sponsor: Chevron Research and Technology Company

Dear Dr. Harper:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above captioned study. Any modifications required for this approval are shown below. The review was carried out by core members.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or any new advertisements. Serious adverse reactions must be reported promptly to the IRB. Progress reports on the research activity are to be submitted every four months.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR Section 21, Parts 50 and 56.

Sincerely.

Robert H. McMaster, M.D.

Chairman

Date 7/12/94

RHM/sll

Modifications: None required.

APPENDIX V

(Total number of pages = 26)

Protocol, Protocol Amendments and Consent Form

PROJ. No. 44. 1399-70
PAGE No. 11 - 1

Ref.: 94-1399-70



REPEATED INSULT PATCH TEST WITH N FINISHED OIL (Modified praize Procedure)

OBJECTIVE

To evaluate inished Oil) for the induction of contact sensitization by repetitive applications to the skin of human volunteers and to report any irritation observed with the test material.

SPONSOR AND MONITOR

INVESTIGATIVE ORGANIZATION, TEST LOCATION AND PERSONNEL

Organization:

Hill Top Research, Inc.

Test Location:

Miamiville, Ohio

Investigator:

Robert A. Harper, Ph.D.

Test Area Supervisor:

Grace E. Kenney, M.S.

Senior Project Leader:

Bonnie Rue

CLINICAL RESEARCH STANDARDS

The clinical investigation, including the informed consent, will be reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board must be obtained prior to the initiation of the investigation.

A properly executed informed consent document in compliance with FDA regulations (21 CFR 50) will be obtained from each subject prior to entering the study.

June 30, 1994

HILL TOP RESEARCH, INC. Page 1 of 9

P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/831-1217



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EXPERIMENTAL DESIGN

The design is an adaptation of the Draize Patch Test.¹ The test of each article consists of the following:

- A. INDUCTION PERIOD Repetitive application of test article to the same site on the skin for approximately three weeks. (Alternate sites are used if test articles evoke irritation under conditions of the test.)
- B. REST PERIOD Following the induction period, the subjects do not receive any application of test article for approximately two weeks.
- C. CHALLENGE Application of test article to a pre-exposed and a naive site to test for reactions indicative of contact sensitization.
- D. RECHALLENGE Application of test article or test article components to naive site to confirm reactions indicative of contact sensitization.

TEST ARTICLES

The Sponsor will furnish the undiluted test article(s) and stipulate each test concentration.

Hill Top Research, Inc. will supply the negative control (Mineral Oil U.S.P.) and all other materials required for the test.

¹J. H. Draize, "Dermal Toxicity," in <u>Appraisal of the Safety of Chemicals in Foods</u>, <u>Drugs and Cosmetics</u>, The Staff of the Division of Pharmacology of the Federal Food and Drug Administration (Austin, Texas: The Editorial Committee of the Association of Food and Drug Officials of The United States, 1959), pg. 52

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TEST ARTICLES (Continued)

| Hill Top Lab Code | Sponsor's Code | Patch Type* | Test As | Method and Quantity of Application to Patch |
|----------------------------|-----------------------|----------------|------------------------------|---|
| A | Mineral Oil U.S.P. | * | Received | 0.1ml by pipette or syringe |
| В | d Oil) | 本 | Received | 0.1ml by pipette or syringe |
| С | (m r musued Oil) | * | 50% in Mineral Oil U.S.P. | 0.1ml by pipette or syringe |

^{*}Semi-occluded using Webril® pads (Professional Medical Products, Inc.) secured on two opposing sides with hypoallergenic tape (Blenderm®).

A 20g sample of the test article will be returned to the Study Monitor for archiving. All remaining test article and remaining dosing mixture(s) (if the test article is administered as a dilution during the main part of the induction phase and/or challenge phase) shall be shipped to the Sponsor upon acceptance of the final report. The sample container will be labeled with the test article name, Sponsor's protocol number, and the Testing Laboratory's study number. Each test article shall be accompanied by a transmittal letter describing the sample contained in the shipment. The test article shall be packed in a suitable container. The sample shall be

telephone acticle and study identification, carrier, waybill number, and estimated time of arrival.

^{**}If additional dose concentrations need to be evaluated, an amendment to the protocol shall be written to include all additional procedures.

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Ref.: 94-1399-70

TEST ARTICLES (Continued)

Application of any of these concentrations will be halted if, in the judgement of the Investigator, irritation production is too great to allow detection of a sensitization response at challenge.

STUDY POPULATION

A sufficient number of healthy adult male/female subjects will be enrolled to ensure a minimum of 20 subjects complete the study. The subjects will be required to give written informed consent and to complete a brief demographic/medical questionnaire before taking part in the study. The investigative staff are to exclude volunteers from entrance into the study for any of the following reasons:

- Insulin-dependent diabetes.
- Mastectomy for cancer involving removal of lymph nodes within the past year.
- Active clinically significant skin diseases which may contraindicate participation, including eczema and atopic dermatitis.
- · Participation in any patch test for irritation or sensitization within the last four weeks.
- Routine high dosage use of anti-inflammatory drugs (aspirin, ibuprofen, corticosteroids), immunosuppressive drugs or antihistamine medications (steroid nose drops and/or eye drops are permitted).
- Severe asthma.
- Immunological disorders such as HIV positive, AIDS and systemic lupus erythematosus.
- Use of topical drugs at patching site.
- Pregnant or lactating women.
- Known sensitivity to lubricant oils or products.
- Daily exposure to lubricant oils or products.
- Known allergy to detergents, sulfa containing products, or sulfonates.

No demographic profile is specified by protocol, except that each subject must be 21-60 years of age.

Anyone who is absent more than once during the induction phase or at any time during the challenge week will be withdrawn from further participation in the study. Subjects failing to complete the study will be identified and, whenever possible, a reason will be given.

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TREATMENT ASSIGNMENTS

Each subject will test either Test Article B or C and the negative control (Test Article A). A total of two test areas are available for application of the test kit to the deltoid region of the upper arm. Each test area is functionally subdivided into four individual patch sites: the original (O), move (M and M-1) and challenge patch (A) application sites. Each area is assigned as a block of four horizontally arranged contiguous sites on the surface of the skin (an overall area of approximately 4 1/2cm by 22cm).

The assignment of the two test areas to individual test articles within the test kit will be rotated sequentially within the panel. During induction, test articles will be repeatedly applied to the same test area on each subject. Within each test area, the individual test articles will be repetitively applied to the same site if the test article is well tolerated.

PROCEDURE

The test kit for each subject will contain one test article and one control test article. Each test day, patches will be prepared fresh according to the specifications presented in the <u>TEST ARTICLES</u> section. All patches will be applied by the laboratory staff but removed by the individual subject.

Each test article in the test kit will be applied to sites on the skin of the deltoid region of the upper arm for a contact period of 24 ± 1 hours per application. Induction applications will be made three times per week (on Monday, Wednesday and Friday) for three successive weeks. The nine applications made during these three weeks will be termed Induction Application Nos. 1 through 9, respectively. During the fourth week (on Monday), any subject who is absent for one of the regularly scheduled induction applications will receive a make-up induction application.

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PAGE No. 11 C:

Ref.: 94-1399-70

PROCEDURE (Continued)

All induction applications for an individual test article will be made to the same site (the site receiving the original test article at Induction Application No. 1) unless reactions become so strong as to make this inadvisable. Assessment of a score of Grade 2 or greater is considered to be a strong reaction. In this case, subsequent applications of the offending test article will be made to an adjacent area, and a second change of site will be made if a second strong reaction occurs. If a third strong reaction to the test article is manifested, patches of this test article will be discontinued until after the rest period has been completed. The use of a first and second adjacent site will be identified on the source document as M and M-1 sites, respectively, to indicate movement of test site from the original (O) application site.

A 10 to 17-day rest period will follow the final induction application. Following the rest period, on Monday of the sixth week, a challenge application of the test article(s) in the test kit will be made to each subject. During the challenge application, the test articles will remain in contact with the skin for a period of 24 ± 1 hours. Challenge will consist of application to a naive site located away from the original (O) application site (e.g., opposite arm or opposite side of the back). Simultaneous application to a pre-exposed site (i.e., the original site used for Induction Application No. 1) will be made concurrently with the challenge at a naive site. If the presence of a residual reaction at any of the induction sites makes application of the challenge patch to an adjacent naive site inadvisable, an alternate naive site on the deltoid region of the upper arm may be used and is documented in the test records and the report.

Observations at a naive site will provide a basis for an interpretation of contact sensitization. Data obtained from the challenge patch applied to a pre-exposed site will be reported and used to support the conclusions drawn from observations at the naive site. Positive reactions at a pre-exposed site will not be interpreted as significant evidence of contact sensitization unless confirmed by observations at a naive site.

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PAGE No. 1 7

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EVALUATIONS

Reactions will be scored Monday, Wednesday and Friday, 48 or 72 hours after each induction application (24 or 48 hours after patch removal); 48 hours and 96 hours after challenge application (24 and 72 hours after patch removal).

Skin responses to each patch application will be examined and graded under light supplied by a 100-watt incandescent blue bulb. On any group of subjects, the same scorer will carry out all evaluations of the test sites. All reasonable attempts will be made to ensure that the same individual will do all scoring of test sites during the course of the study. The scorer will be blinded as to the treatment assignments. Reactions to the test articles are to be documented on the source document by the numerical and letter grade scoring system defined in this protocol (See attached Scoring Scale). In instances where a strong reaction warrants application of the test article to the M or M-1 site, residual scores will be recorded through to the end of the study for all previously exposed sites.

ADVERSE EVENT/PATCH SITE DEFINITION

An adverse event is any unusual or unexpected reaction that occurs during the study. The subject, under the direction of the Investigator (or designee), is referred to Hill Top's Consultant Physician for treatment. All adverse events are monitored by the Hill Top Staff until resolution.

REPORT

The final report will identify the number of subjects completing the study and summarize the data and conclusions relative to observations made with these subjects. Source data will be retained by Hill Top Research, Inc. on microfilm. All raw data and the original final report will be returned to the Sponsor.

A copy of the original source data will be maintained according to the Investigators standard operating procedure. Copies of transcribed typed data tables will be incorporated into the final report as data tables along with but not limited to the following:

(a) A summary that includes a brief description of the methods and highlights all positive findings and any deviations from control data that may be indicative of toxic effects.

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REPORT (Continued)

- (b) A Quality Assurance Statement, including inspection dates of critical phases of the study, signed by the Testing Laboratory's Quality Assurance Unit.
- (c) Name and address of the Testing Laboratory and names and signatures of all responsible personnel.
- (d) A methods section including a complete description of: test article; data evaluation; test system; test article preparation and administration; scoring; statistical methods; dates of study initiation (date of Investigator's signature), experimental start and termination dates; procedures for the storage of raw data final report, and a retain sample of the test article.
- (e) A results section including a discussion of evaluation of test results.
- (f) The final report appendices will include a copy of the protocol, all protocol amendments, and a list of all protocol deviations and their effect on the outcome of the study.

MOTICE

No modifications of the protocol will be permitted without the written approval from the Sponsor, the IRB Chairman and the Investigator. Such changes must be documented in writing as soon as possible in the form of any amendment that is to be attached to the final protocol. In the event and immediate alteration to the protocol is required, the change shall be made and documented by the Investigator after seeking verbal approval from the Sponsor, the IRB Chairman and the Investigator. Written approval in the form of an amendment to the protocol will follow and be attached to the final protocol.

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| | |

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PROTOCOL APPROVAL

HILL TOP RESEARCH, INC.

Principal Investigator:

Robert A. Harper, Ph.D.

6/30/94 Date

General Manager:

Ralph Anderson

Date

Sponsor's Monitor/Representative:

ref.: \patch\projects\941399.pro

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SCORING SCALE AND DEFINITION OF SYMBOLS USED IN TABULATING DATA

Reactions to the test materials are scored according to the following scale.

Each of the scores represents the presence of a clinically significant characteristic localized in a representative portion of the patch area, that is 25% or more of the patch site. Questionable (barely perceptible, minimal or involving less than 25% of the patch site) reactions are inconclusive and are not recorded except in diary format (the latter is furnished at the discretion of the patch scorer).

- 0 = No visible reaction and/or erythema
- 1 = Mild reaction macular erythema (faint, but definite pink)
- 2 = Moderate reaction macular erythema (definite redness, similar to a sunburn)
- 3 = Strong to severe reaction macular erythema (very intense redness)

Definition of letter grades appended to a numerical grade:

- E = Edema swelling, spongy feeling when palpated
- P = Papules red, solid, pinpoint elevations, granular feeling like, diameter 5mm or less
- V = Vesicles small elevation containing serous fluid (blister-like), diameter 5 mm or less
- B = Bulla reaction fluid-filled lesion greater than 5mm in diameter
- S = Spreading evidence of the reaction beyond the Webril® pad area
- Weeping result of a vesicular or bulla reaction serous exudate clear fluid oozing or covering patch site
- I = Induration solid, elevated, hardened, thickening skin reaction

Definition of superficial observations appended to a numerical and/or letter grade:

- g = Glazing
- y = Peeling
- c = Scab, dried film of serous exudate of vesicular or bulla reaction
- d = Hyperpigmentation (reddish-brown discoloration of test site)
- h = Hypopigmentation (loss of visible pigmentation at test site)
- f = Fissuring grooves in the superficial layers of the skin
- (C) = Additional comments appear below or on the following page

Applications must either be terminated or moved to naive adjacent sites if a score of Grade 2 or greater is observed.

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SCORING SCALE AND DEFINITION OF SYMBOLS USED IN TABULATING DATA (Continued)

Symbols used in tabulating data (in addition to scoring grades):

- O Original application site (first induction application).
- M Adjacent site for application after first strong reaction during induction.
- M-1 Second adjacent site for application after second strong reaction during induction.
- A Naive adjacent site used during challenge application.
- NP Number of subjects not included in score totals: (see * below).
- MU Make-up session for subjects with earlier absence(s).

Symbols used to document deviation from experimental plan:

- R Applied to adjacent site because of adhesive reaction or for other reasons irrelevant to test material reactions.
- X Patch omitted due to previous strong test reaction(s).
- XR Patch omitted for reasons unrelated to the test.
- L Test patch worn less than 23 hours.
- Subject absent.
- * Residual reaction to earlier application after absence. (Not included in score totals.)
- N9G No ninth grade.

Institution: Hill Top Research, Inc. Investigator: Robert A. Harper, Ph.D.

Study Title: Human Repeated Insult Patch Test (Pilot Study)

Project No.: 94-1399-70

INFORMED CONSENT STATEMENT

INTRODUCTION: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made as to the results of the study.

<u>PURPOSE OF STUDY:</u> This study involves research to see if the test articles (samples) can be put on human skin for long periods of time without causing irritation or allergies. Approximately 20 people will be involved in the study. The duration of the study is scheduled for six weeks but this could be extended if irritation or allergies are observed. Each participant will test one test article and a vehicle control. The test article is classified as a lubricant oil product.

STUDY PROCEDURES: The test articles will be placed on patches (small adhesive squares with a cotton pad). The patches will be put on the upper arm. Each patch will stay on your skin for 24 hours. Fresh patches will be applied nine times during the first three weeks followed by a 10-14 day rest period. On Monday of the sixth week, a double set of patches will be applied. You will come to the test location 13 times in six weeks.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing or trying to get pregnant. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study, and at the beginning of Week 4 and 6. You must also agree to use an adequate means of birth control.

RISKS: Since the test is being done to see how the test articles affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin. On some occasions the reactions may spread beyond the patch.



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PAGE No. 12-16

Informed Consent Statement Page 2

Project No.: 94-1399-70

RISKS: (Continued)

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test articles or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy.

BENEFITS: The participants in this study will not benefit from the application of the test articles. But the results may all allow a new or improved product to be marketed.

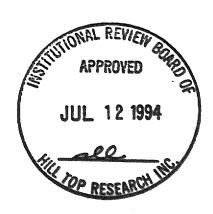
<u>ALTERNATIVE PROCEDURES:</u> Because this is a safety study, alternative procedures are not applicable.

<u>CONFIDENTIALITY:</u> Hill Top Research will keep confidential, information concerning you that is obtained in connection with this study, except the Company whose product is $b\epsilon$ ing tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If, in the course of this study you experience illness, discomfort or injury, which appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research has elected to secure workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case emergency, contact Bonnie (Senior Project Leader) at 831-3114, ext. 2311 during business hours (M-F, 8 A.M.- 5 P.M.) or 249-2033 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114 or 1-800-669-1947.



Informed Consent Page 3

PROJ. No. 1399-75
Project No.: 94-1399-70

INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out on my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I've completed as outlined in the attached payment schedule. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am twenty-one years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this consent statement.

| SUBJECT FULL NAME PRINTED ADDRESS | | | |
|-----------------------------------|--------------------|--------|---|
| CITY | STATE | ZIP | |
| TELEPHONE NUMBER | SOCIAL SECURITY | NUMBER | |
| SUBJECT SIGNATURE | | DATE | - |
| WITNESSED BY | | DATE | |
| SUBJECT NUMBER _ | | | |

Ref.: \patch\projects\941399.con



Institution: Hill Top Research, Inc. Project No.: 94-1399-70
Investigator: Robert A. Harper, Ph.D. Page No.:

Study Title: Human Repeated Insult Patch Test (Full Panel)

INFORMED CONSENT STATEMENT REVISION #1

<u>INTRODUCTION</u>: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made as to the results of the study.

<u>PURPOSE OF STUDY:</u> This study involves research to see if the test articles (samples) can be put on human skin for long periods of time without causing irritation or allergies. Approximately 90 people will be involved in the study. The duration of the study is scheduled for six weeks but this could be extended if irritation or allergies are observed. Each participant will test one test article and a vehicle control. The test article is classified as a lubricant oil product.

STUDY PROCEDURES: The test articles will be placed on patches (small adhesive squares with a cotton pad). The patches will be put on the upper arm. Each patch will stay on your skin for 24 hours. Fresh patches will be applied nine times during the first three weeks followed by a 10-14 day rest period. On Monday of the sixth week, a double set of patches will be applied. You will come to the test location 13 times in six weeks.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing or trying to get pregnant. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study, and at the beginning of Week 4 and 6. You must also agree to use an adequate means of birth control.

RISKS: Since the test is being done to see how the test articles affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin. On some occasions the reactions may spread beyond the patch.

Informed Consent Statement Page 2

Project No.: 94-1399-70

RISKS: (Continued)

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test articles or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy.

BENEFITS: The participants in this study will not benefit from the application of the test articles. But the results may all allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES: Because this is a safety study, alternative procedures are not applicable.

CONFIDENTIALITY: Hill Top Research will keep confidential, information concerning you that is obtained in connection with this study, except the Company whose product is being tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If, in the course of this study you experience illness, discomfort or injury, which appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research has elected to secure workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case emergency, contact Bonnie (Senior Project Leader) at 831-3114, ext. 2311 during business hours (M-F, 8 A.M.- 5 P.M.) or 249-2033 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114 or 1-800-669-1947.

Informed Consent Page 3

Project No.: 94-1399-70

pg #

INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out on my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I've completed as outlined in the attached payment schedule. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am twenty-one years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this consent statement.

| SUBJECT FULL NAME PRINTED ADDRESS | | | |
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| SUBJECT NUMBER | | | |

Ref.: \patch\projects\941399.con

Institution: Hill Top Research, Inc. Investigator: Robert A. Harper, Ph.D.

Study Title: Human Repeated Insult Patch Test (Full Panel)

Project No.: 94-1399-70 Page No.:

INFORMED CONSENT STATEMENT REVISION #1

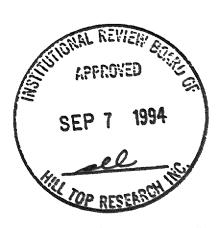
INTRODUCTION: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. It is important for you to understand that no guarantees or assurances can be made as to the results of the study.

<u>PURPOSE OF STUDY:</u> This study involves research to see if the test articles (samples) can be put on human skin for long periods of time without causing irritation or allergies. Approximately 90 people will be involved in the study. The duration of the study is scheduled for six weeks but this could be extended if irritation or allergies are observed. Each participant will test one test article and a vehicle control. The test article is classified as a lubricant oil product.

STUDY PROCEDURES: The test articles will be placed on patches (small adhesive squares with a cotton pad). The patches will be put on the upper arm. Each patch will stay on your skin for 24 hours. Fresh patches will be applied nine times during the first three weeks followed by a 10-14 day rest period. On Monday of the sixth week, a double set of patches will be applied. You will come to the test location 13 times in six weeks.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing or trying to get pregnant. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study, and at the beginning of Week 4 and 6. You must also agree to use an adequate means of birth control.

RISKS: Since the test is being done to see how the test articles affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin. On some occasions the reactions may spread beyond the patch.



Project No.: 94-1399-70

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RISKS: (Continued)

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test articles or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy.

BENEFITS: The participants in this study will not benefit from the application of the test articles. But the results may all allow a new or improved product to be marketed.

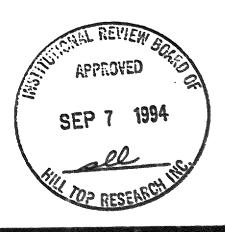
ALTERNATIVE PROCEDURES: Because this is a safety study, alternative procedures are not applicable.

CONFIDENTIALITY: Hill Top Research will keep confidential, information concerning you that is obtained in connection with this study, except the Company whose product is being tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If, in the course of this study you experience illness, discomfort or injury, which appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research has elected to secure workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case emergency, contact Bonnie (Senior Project Leader) at 831-3114, ext. 2311 during business hours (M-F, 8 A.M.- 5 P.M.) or 249-2033 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114 or 1-800-669-1947.



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Project No.: 94-1399-70

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INFORMED CONSENT

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out on my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I've completed as outlined in the attached payment schedule. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am twenty-one years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this consent statement.

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Ref. No.: 94-1399-70

October 21, 1994

PROTOCOL AMENDMENT NO. 2.

The following changes apply to the protocol:

- 1) Test Article B will be applied under <u>semi-occluded</u> conditions to the 90 additional subjects empaneled. The patch condition was listed incorrectly in Protocol Amendment No. 1.
- 2) The Primary Coordinator of the study will be Martha E. Plaza, Test Operations Supervisor, rather than Grace E. Kenney, Test Area Supervisor.

Submitted by: Martha E. P.

Martha E. Plaza, M.B.A.

10/24/94 Data

Test Operations Supervisor

Approved by:_

Robert A. Harper, Ph.I

Date

Investigator

APPROVED

OCT 2 5 1994

LILL TOP RESEARCH: 1150

For Robert McMaster, M.D. Date Institutional Review Board Chairman





Ref. No.: 94-1399-70

December 6, 1994

PROTOCOL AMENDMENT NO. 3

Subject No. 31 will participate in a confirmatory rechallenge. The subject will be patched to Test Article B on original (right arm) and naive (lower back) sites. The patches will be worn for 24 hours and removed by the subject. Scoring of the sites will be at 48 and 96 hours after application.

Submitted by:

Martha E. Plaza, M.B.A

Date

Test Operations Supervisor

Approved by:

Robert A. Harner Ph.D.

Date

Investigator

Robert McMaster, M.D. Date

Institutional Review Board Chairman



Institution:

Hill Top Research, Inc.

Investigator:

Robert A. Harper

Study Title:

Confirmatory Rechallenge

Proj. No.: 94-1399-70

Page No.:

INFORMED CONSENT STATEMENT

<u>INTRODUCTION:</u> Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the study procedures. This study is designed to see if test articles can be put on human skin without causing irritation or allergies.

<u>PURPOSE OF STUDY:</u> You recently took part in a patch test for Hill Top Research, Inc. This study involves follow-up research to see if the test articles caused irritation or allergies. The duration of the study is scheduled for one week but this could be extended an additional one or two weeks if reactions are experienced. You will test two test articles classified as lubricant oil products.

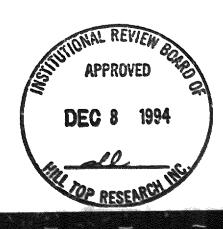
STUDY PROCEDURES: The test articles will be put on your right arm and lower back with patches (small adhesive squares with cotton pads). The test articles are on the pads. Each pad will stay on your skin for 24 hours. You will remove the patches at home. The skin sites will be evaluated on Day 2 and 3. You will come to the test location three times in five days.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent, you must agree to have a urine pregnancy test at the start of the study and at the end of the study. You must also agree to use an adequate means of birth control.

RISKS: Since the test is being done to see how the samples affect human skin, it is possible that you might have a "reaction". A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, small blisters. Reactions usually occur only where the patch pad touches the skin.

Certain subjects, because of their reactions, may be asked to participate in further evaluations of the test products or their components. These further evaluations will consist of applying the materials under patches or to small areas of your skin. You will be contacted individually to request your participation in this type of study should it be necessary.

No risks to study participants, other than those described above as "reactions", are anticipated during the study. Such reactions may be due to skin irritation or allergy. However, the chance of an allergy is considered unlikely.



Informed Consent Statement Page 2

BENEFITS: The participants in this study will not benefit from the application of test materials but the test results may allow a new product to be marketed.

<u>ALTERNATIVE PROCEDURES:</u> Because this is a safety study, alternative procedures are not applicable.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, Inc., except that the Company whose product is being tested will receive a copy of the study. In addition, the Food and Drug Administration and others in certain legal actions may inspect the records of the study.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be the result of the study, Hill Top Research, Inc. will provide you with medical care at no cost to you. Provision of such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the Investigator or Study Manager who will discuss it with you to determine if it has been caused by your participation in the study.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. Pursuant to Ohio law, Hill Top Research, Inc. has elected to secure workers' compensation coverage for participants in its studies and tests and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

If you have any questions about this study or in case of emergency, contact Bonnie (Project Leader at 831-3114, ext. 2810 during business hours (M-F, 8am - 5pm) or 249-2036 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Hill Top Institutional Review Board, Dr. McMaster, Chairman, at 831-3114.

<u>VOLUNTARY PARTICIPATION:</u> Your decision to participate in this research study is strictly voluntary. Your refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled.



Proj. No.: 94-1399-70

INFORMED CONSENT

Proj. No.: 94-1399-70

I understand that I will be paid the amount stated in the attached payment schedule for completion of this study. I know that participation is voluntary and that I have the right to refuse to participate. I know that I may drop out at any time without penalty or loss of benefits to which I am otherwise entitled. If I drop out of my own accord for personal reasons or am dismissed for refusal to obey rules or follow directions, I will only be paid for the portion of the test that I have completed as outlined in the attached payment schedule. If, in the judgement of the Investigator, it is best to discontinue my participation in the study for other reasons, I will either be paid in full or for that portion of the test already completed as shown on the attached payment schedule.

If I am a female of childbearing potential, I am not now pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

I have read all the above information and was given an opportunity to ask questions about any part of it. Answers to such questions (if any) were satisfactory. I am 18 years of age or older and freely and without reservation give my informed consent to serve as a subject in this study. I have received a copy of this informed consent.

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| WITNESSED BY | DATE |
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| | DEC 8 1994 |
| | |

HILL TOP RESEARCH, INC.

IMPORTANT NOTICE

Hill Top Research, Inc. submits this report with the understanding that no portion of it will be used for advertising or promotion without obtaining our prior written consent to the specific proposed use. Vhen such use is desired we will be glad to assist in the preparation of mutually acceptable excerpts or summaries.

TEST ARTICLE PROCEDURE

Unless the Sponsor requests otherwise, it is Hill Top Research's practice to store test articles for one (1) month after a study is concluded. The test articles are then destroyed.

New drugs and investigational devices are handled on an individual basis as worked out with the Sponsor.

DATA RETENTION

All study documents and the original final report will be on file in the Hill Top Companies archives for a period of not less than two years, unless indicated otherwise on the Study Sumn.ary and Authorization Form. A permanent record will be retained in the form of microfilm.

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August 9, 1994

Protocol Amendment No. 1

At least 90 additional subjects will be empaneled to evaluate the potential for Test Article B to elicit contact sensitization under occluded conditions. These additional subjects will complete a full 100 plus panel for this test article. Subjects will also receive Test Article A (mineral oil).

Submitted by:

est Area Supervisor

Approved by:

Investigator

IRB Chairman

Best Available Copy



Ref.: 94-1399-70

HILL TOP RESEARCH, INC.

P.O. Box 429501 · Cincinnati, Ohio 45242 · 513/831-3114 · Fax 513/

